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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2021–ICEB–2021–0012]

Privacy Act of 1974: Implementation of Exemptions; U.S. Department of Homeland Security/U.S. Immigration and Custom Enforcement–018 Analytical Records System of Records

AGENCY: U.S. Immigration and Custom Enforcement U.S. Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The U.S. Department of Homeland Security (DHS) is issuing a final rule to amend its regulations to exempt portions of a newly established system of records titled, ''DHS/U.S. Immigration and Customs Enforcement (IC)–018 Analytical Records System of Records'' from certain provisions of the Privacy Act. Specifically, the Department exempts portions of the system of records'' from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: This final rule is effective November 8, 2021.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Jordan Holz, *ICEPrivacy@ice.dhs.gov,* Privacy Officer, U.S. Immigration and Customs Enforcement (ICE), 500 12th Street SW, Mail Stop 5004, Washington, DC 20536. For privacy issues please contact: Lynn Parker Dupree (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Department of Homeland Security (DHS) U.S. Immigration and Customs Enforcement (ICE) published a notice of proposed rulemaking in the **Federal Register**, (86 FR 15134, March 22, 2021), proposing to exempt portions of the system of records titled, ''DHS/ICE–018 Analytical Records'' from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. The DHS/ICE–018 Analytical Records system of records notice was published concurrently in the **Federal Register**, (86 FR 15246, March 22, 2021), and comments were invited on both the Notice of Proposed Rulemaking (NPRM) and System of Records Notice (SORN).

Public Comments

DHS received four comments on the NPRM, two of which also referenced the SORN.

NPRM

All comments related to the NPRM state that exempting the SORN from portions of the Privacy Act will restrict the public's ability to demand transparency regarding ICE analytical systems.

The first concern commenters presented was that ICE's claiming of Privacy Act exemptions create a lack of transparency in ICE operations and the analytical systems themselves, stating: ''[t]he American public has the right to know how our tax dollars are being spent and if their tax dollars are being spent wisely and ethically in regards to immigrants'' and ''[e]xemptions under the Privacy Act will not just protect DHS' system of records but also the data, software, and systems owned by private companies, perpetuating further a lack of transparency in deportations and other investigations under the guise of 'national security.' ''

As discussed in the SORN and below, individuals about whom ICE maintains information in its records systems may still submit a Privacy Act amendment request or a request for access to information. While ICE has exempted this system of records from the access and amendment provisions of the Privacy Act, it will still consider these requests on a case-by-case basis to ensure that agency data is complete, accurate, and current.

Further, to provide the greatest access to information, ICE considers individuals' requests under both the Privacy Act and the Freedom of Information Act (FOIA). To this end, the public can seek records described in the Analytical Records SORN under FOIA. In contrast to the broad scope of FOIA, 5 U.S.C. 552, the Privacy Act is narrowly focused on individuals' personal information maintained in agency systems of records. As stated in the comment, the Privacy Act is meant to ''. . . ensure accuracy of and individuals' access to information that agencies gather about them.'' FOIA's broad scope allows the public access to governmental information generally. This includes information on data, systems, and connections within the agency. Subsections (t)(1) and (t)(2) of the Privacy Act prohibit agencies not only from restricting an individual's access to his/her record under FOIA based solely on claimed Privacy Act exemptions, but also from withholding records under the Privacy Act based on FOIA exemptions. Information about filing a FOIA request with ICE is available at *www.ice.gov/foia.*

The publication process for the Analytical Records SORN as required by the Privacy Act promotes the accountability, responsibility, legislative oversight, and open government requested by commenters. Subsection (r) of the Privacy Act requires agencies, when establishing or significantly modifying a system of records, to provide adequate advance notice to the Office of Management and Budget (OMB), the Committee on Oversight and Government Reform of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate. This advance notice is separate from the public comment period ICE is engaging in here. The advanced notice that ICE provided to OMB and the committees of jurisdiction in Congress allows each body to make an evaluation of the probable or potential effects of ICE's proposal on the privacy or other rights of individuals.

Finally, in addition to the publication of SORNs here in the **Federal Register**, ICE also provides transparency into its systems through the publication of Privacy Impact Assessments (PIA). PIAs are conducted in accordance with the E-Government Act of 2002 (Pub. L. 107–347) by ICE Privacy personnel, are reviewed by the DHS Privacy Office, and signed by the DHS Chief Privacy Officer. PIAs describe how ICE

information technology systems work, what information they collect, how ICE uses that information, any external parties with whom the information is shared, and the privacy risks and corresponding mitigations employed by ICE. ICE and all DHS PIAs are published on the DHS website, *www.dhs.gov/privacy.*

The second concern raised by commenters is the perceived inability for an individual to access ICE records about him/her due to the exemptions claimed in this rule. Commenters state ''[e]xemptions intended to prevent the subject of an investigation from being aware of the investigation undermine the presumption of innocence enjoyed by individuals in the United States by proposing that individuals being investigated should be denied rights . . .'' and that they ''. . . take exception to the fact that the DHS is not required to establish requirements, rules, or procedures with respect to such access.'' The commenters' concern is amplified as the exemptions may not just apply to individuals under investigation, but their associates and family members as well.

As recognized in the comments, DHS is exempting this system as law enforcement sensitive to ensure that information and records produced in response to Privacy Act requests are not used to disrupt or frustrate ICE investigations. As stated in the accompanying SORN, ''DHS/ICE will consider individual requests to determine whether or not information may be released.'' ICE will consider all Privacy Act requests, whether access or amendment requests, on a case-by-case basis. As such, ICE has established access requirements, rules, and procedures outlined in the SORN accompanying this rule. The Privacy Act exemptions claimed here in no way alter or abrogate an individual's due process and fair trial rights guaranteed by the U.S. Constitution.

SORN

The comments filed in response to the proposed rule also raised objections regarding the DHS/ICE–018 Analytical Records SORN. Two objections are outside the scope of this rulemaking and so will not be addressed here. One objection from a commenter is that the SORN does not examine ICE's relationship with a private software vendor. ICE will not respond to this objection as a final rule is not the proper forum to discuss ICE contractual relationships. Additionally, ICE will not examine U.S. Citizenship and Immigration Services' (USCIS) biometrics NPRM, as requested by a commenter, as that proposed rule has been withdrawn (86 FR 24750, May 10, 2021).

The comments ICE received on the SORN were focused on four distinct areas of concern: (1) The SORN expands ICE's existing authority and ability to collect records on individuals; (2) The SORN lacks transparency, in that the SORN did not address issues important to the commenters; (3) ICE analytical systems use artificial intelligence and machine learning, with specific concern that these analytical systems will be used for ''predictive policing'' or ''constant and ongoing surveillance of immigrants and citizens;'' and, (4) The SORN's routine uses are so overly broad that ''they provide no limit on permissible sharing.''

The Analytical Records SORN Expands ICE's Existing Records Collection

A commenter expressed concern that the Analytical Records SORN was ''expanding the sources from which data is gathered as well as the categories of individuals covered and records included and allows use of algorithmic processes.'' ICE did not intend the SORN to be understood as solely a consolidation of two previously published SORNs. Rather, as stated in the background section of the SORN, ICE is establishing a new system of records that clarifies and more accurately reflects the nature of records ICE collects, maintains, processes, and shares in large analytical data environments.

The purpose for ICE's publication of the Analytical Records SORN is to give the public notice of the types of records ICE maintains in support of analytical and algorithmic processes. Information derived from the ICE Tip Line and trade data, previously covered by the DHS/ICE–016 FALCON-Search and Analysis (FALCON–SA) SORN and DHS/ICE–005 Trade Transparency and Research (TTAR) SORN, respectively, are now covered under the Analytical Records SORN. Beyond those two categories of information, the Analytical Records SORN does not provide stand-alone coverage for any other ICE collection efforts. As stated in the SORN, ICE analytical systems ingest data collected through other efforts and authorities and covered by other SORNs. Differences in the categories of individuals or records described in the DHS/ICE–016 FALCON–SA SORN and DHS/ICE–005 TTAR SORN and those described in the Analytical Records SORN are reflective of these other ingestions.

The SORNs covering the ingested information restrict ICE's use of that information to what is compatible with the original purpose of the collection. Technological advancements allow ICE to institute protections at the record level that follow the data as it passes from the originating systems into ICE analytical systems. As such, the initial protections and restrictions on the use and sharing of the ingested information as described in those originating SORNs are retained by ICE as a record is ingested into its analytical systems. To reiterate an example given in the SORN, data available through an ingest from ICE's Investigative Case Management System (ICM) would be covered by the DHS/ICE–009 External Investigations SORN (85 FR 74362, November 20, 2020) and each record stored from that ingest is tagged as belonging to that system of record. An analytical system may filter, search, graph, or link that data with other datasets, but only for a purpose described in DHS/ICE–009, such as generating leads for investigations. If ICE personnel wish to share an analytical product from an ICE analysis system with a third party, the tags of the underlying data, and its accompanying restrictions, must similarly be respected. Therefore, ICE analytical systems covered by the Analytical Records SORN do not expand ICE collections, use, or sharing of personal data.

The Analytical Records SORN Does Not Provide an Adequate Accounting of DHS Collection, Use, and Sharing of Data

The commenters maintain that the Analytical Records SORN does not describe the access controls and auditing mechanisms within ICE's analytical systems in sufficient granularity. They also raise objections that the SORN does not discuss different analytical systems, such as ICE's FALCON–SA system and ICE's ''complex network of interlocking systems'' including ICE's connections to DHS's Homeland Advanced Recognition Technology system (HART).

The publication of the Analytical Records SORN is an effort to provide broader transparency of the ICE analytical environment so that ICE does not continue to rely on disparate and segregated notices from previously-published SORNs. The Analytical Records SORN reflects the realities of cloud computing and modern technological processes, where access and control are derived from user privileges rather than the physical location of data. As stated in the SORN, ICE's analytical processes may span multiple information technology systems within the ICE domain and records may be derived from multiple

collection points. Moreover, the purpose of a SORN is to provide notice to the public regarding personally identifiable information maintained by an agency; it is not meant to outline or provide a full description of the technical capabilities and nuances of an IT system. Granular detail of system connections, algorithmic processes, access controls, and auditing functions can be found in the applicable system's PIA, which can be found at *www.dhs.gov/privacy.* All PIAs link to their associated SORN(s), providing clear notice as to which systems are covered under the Analytical Records SORN.

The SORN Allows for ICE To Conduct Unlimited Surveillance and ''Predictive Policing''

Several commenters expressed concern with ICE's use of advanced analytics and artificial intelligence to engage in controversial policing tactics. The first tactic, ''predictive policing,'' is the practice of using statistics and analysis to forecast crime or identify where crime may occur in the near future.[1] Certain state or local police departments have used these methods to determine where to deploy resources or to identify those who are likely to commit crimes in the future by examining past behaviors.

The Analytical Records SORN does not support predictive policing. The SORN lists the purposes of the collection, use, and sharing of information in ICE analytical systems. The purposes of the systems are to identify current violations of law and regulation or generate leads for ongoing investigations. There is no purpose stated in the SORN that allows for its systems to engage in future state risk modelling.

Commenters expressed concern with a second controversial policing tactic, ''ongoing and constant surveillance of immigrants and citizens.'' This is similarly not supported by the Analytical Records SORN. As stated in the SORN and above, the Analytical Records SORN does not expand ICE collections of personal data. ICE analytical systems ingest data that has already been collected through other efforts and authorities. The restrictions on use of that data are listed in the SORN relevant to that collection and are transferred to the ICE analytical systems for linkage and further analysis. ICE analytical systems are meant to process data that has already been collected in a more efficient manner using advanced analytics and modern processing techniques. They are not used to monitor or surveil the public.

The SORN's Routine Uses Are Overly Broad

Finally, a commenter objected that the routine uses listed in the Analytical Records SORN are ''so expansive . . . they provide no limit on permissible sharing.'' The commenter, unfortunately, has not articulated any specific routine use that is inconsistent with the Privacy Act or ICE's statutory authorities for ICE to address. Generally, however, any routine use listed in the SORN must be compatible with the purpose of the system of records, as stated in the SORN, the purpose for which ICE originally collected the information, and ICE's statutory mission. Each routine use is analyzed and vetted for compatibility by ICE and DHS. As the Analytical Records SORN consolidates two previous ICE SORNs, the vast majority of routine uses in the new Analytical Records SORN are the same as the routine uses listed in those previously published SORNs. This means that the Analytical Records SORN routine uses were examined on multiple occasions by government oversight bodies that determined they were neither overly broad nor outside the stated purpose of the system of records.

As described in the SORN, if data is ingested from another system of records, the ICE analytical system, through record tagging and controls, ensures any subsequent sharing is compatible with the original SORN's purposes. This provides additional safeguards in the flow of information and limits the permissible sharing of data.

After consideration of public comments, the Department will implement the rulemaking as proposed.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS amends Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.;* Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. In appendix C to part 5, add paragraph 86 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

86. The DHS/ICE–018 Analytical Records System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/ICE–018 Analytical Records System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; national security and intelligence activities. The DHS/ICE–018 Analytical Records System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other Federal, State, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security has exempted this system from the following provisions of the Privacy Act, subject to limitations set forth in 5 U.S.C. 552a(c)(3) and (4), (d), (e)(1), (e)(2) and (3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8); (f); and (g) pursuant to 5 U.S.C. 552a(j)(2). Additionally, the Secretary of Homeland Security has exempted this system from the following provisions of the Privacy Act, subject to limitations set forth in 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (f) pursuant to 5 U.S.C. 552a(k)(2). Where a record received from another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here. Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) and (4) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access and Amendment to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to

[1] Tim Lau, Predictive Policing Explained (April 1, 2020), *available at https://www.brennancenter.org/our-work/research-reports/predictive-policing-explained.*

avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities. Further, permitting amendment to counterintelligence records after an investigation has been completed would impose an unmanageable administrative burden. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsection (e)(2) (Collection of Information from Individuals) because requiring that information be collected from the subject of an investigation would alert the subject to the nature or existence of the investigation, thereby interfering with that investigation and related law enforcement activities.

(e) From subsection (e)(3) (Notice to Subjects) because providing such detailed information could impede law enforcement by compromising the existence of a confidential investigation or reveal the identity of witnesses or confidential informants.

(f) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

(g) From subsection (e)(5) (Collection of Information) because with the collection of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely, and complete.

(h) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(i) From subsection (g)(1) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Lynn Parker Dupree,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2021–24328 Filed 11–5–21; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1220

[Document No. AMS–LP–20–0085]

Soybean Promotion and Research: Adjusting Representation on the United Soybean Board

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule adjusts the number of members on the United Soybean Board (Board) to reflect changes in production levels that have occurred since the Board was last reapportioned in 2018. As required by the Soybean Promotion, Research, and Consumer Information Act (Act), membership on the Board is reviewed every 3 years and adjustments are made accordingly. This change results in a decrease in Board membership for one State (Alabama), decreasing the total number of Board members from 78 to 77. These changes are reflected in the Soybean Promotion and Research Order (Order) and will be effective with the Secretary of Agriculture's (Secretary) appointments for terms in the year 2022. This final rule also corrects the number of States and units to the Order. Technical corrections to the regulations adjust the number of States and units from 30 to 31.

DATES: This rule is effective as of December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Sarah Aswegan, (515) 201–5190; *Sarah.Aswegan@usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13563

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule does not meet the definition of a significant regulatory action contained in section 3(f) of E.O. 12866 and therefore, the Office of Management and Budget (OMB) has waived review of this action.

Executive Order 12988

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

Section 11 of the Act (7 U.S.C. 2910) provides that nothing in the Act may be construed to preempt or supersede any other program relating to soybean promotion organized and operated under the laws of the U.S. or any State. There are no administrative proceedings that must be exhausted prior to any judicial challenge to the provisions of this rule.

Executive Order 13175

This proposed rule has been reviewed under E.O. 13175—Consultation and Coordination with Indian Tribal Governments. E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) Policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects 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.

AMS has assessed the impact of this proposed rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under E.O. 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed regulation has been shared during a quarterly call, and tribal leaders were informed about the proposed regulation and the opportunity to submit comments. AMS will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the regulations.

Paperwork Reduction Act

In accordance with OMB regulations (5 CFR part 1320) that implement the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping

requirements contained in the Order and accompanying Rules and Regulations have previously been approved by OMB and were assigned OMB control number 0581–0093.

Background

The Board was initially appointed on July 11, 1991, pursuant to the provisions of the Act (7 U.S.C. 6301–6311), and the Order (7 CFR part 1220) issued thereunder. The Order established an initial Board with 60 members, composed of soybean producers. For purposes of establishing the Board, the United States was divided into 31 States and geographical units. Representation on the Board from each unit was determined by the level of production in each unit.

Reapportionment

Section 1220.201(c) of the Order provides that at the end of each 3-year period, the Board shall review soybean production levels in the geographic units throughout the United States. Section 1220.130 of the Order defines a unit as each State, or group of States, which is represented on the Board. The Board may recommend to the Secretary modification in the levels of production necessary for Board membership for each unit.

Section 1220.201(d) of the Order provides that at the end of each 3-year period, the Secretary must review the volume of production of each unit and adjust the boundaries of any unit and the number of Board members from each such unit as necessary to conform with the criteria set forth in § 1220.201(e): (1) To the extent practicable, States with annual average soybean production of less than 3 million bushels shall be grouped into geographically contiguous units, each of which has a combined production level equal to or greater than 3 million bushels, and each such group shall be entitled to at least one member on the Board; (2) units with at least 3 million bushels, but fewer than 15 million bushels shall be entitled to one board member; (3) units with 15 million bushels or more but fewer than 70 million bushels shall be entitled to two Board members; (4) units with 70 million bushels or more but fewer than 200 million bushels shall be entitled to three Board members; and (5) units with 200 million bushels or more shall be entitled to four Board members.

The Board was last reapportioned in 2018. The total Board membership increased from 73 to 78 members, with Alabama, Kentucky, North Dakota, South Dakota, and Tennessee each gaining one additional member. The final rule was published in the **Federal Register** (83 FR 53365) on October 23, 2018. This change was effective with the 2019 appointments.

This final rule decreases total membership on the Board from 78 to 77, without affecting the overall number of states and regions. Thus, this change will not affect the number of geographical units.

This final rule adjusts representation on the Board as follows:

State	Current representation	Final representation
Alabama	2	1

Board adjustments by this rulemaking will take effect with the Secretary's 2022 appointment process.

This final rule also corrects the number of States and units to the Order. During a previous reapportionment, the final rule did not account for the change in the number of States and units, as New Jersey production levels met the threshold to separate from the Eastern Region. Due to that oversight, AMS is making the correction. Technical corrections to the regulations adjust the number of States and units from 30 to 31.

Summary of Comments

A proposed rule was published in the **Federal Register** (86 FR 19788) on April 15, 2021, with a 60-day comment period. USDA received 10 comments. The comments communicated displeasure for Alabama's decreased number from two seats to one seat. The commenters contend that due to Alabama's lower production levels, compared to the Midwest, the producers do not have as much of a voice for their state and region. Given the Southeast's different climate, soil, and production factors, the commenters feel a second seat would give them stronger representation to help with issues that are specific to Alabama and the Southeast. Leaving the Alabama seat at two would not be consistent with the Act and Order, which requires that at the end of each 3-year period, the Secretary review the volume of production of each unit and adjust the boundaries of any unit and the number of Board members from each such unit as necessary to conform with the formula to determine the number of directors for each unit set forth in § 1220.201(e). This was done by calculating production data for years 2015–2019 (excluding the crops in years in which production was the highest and in which production was the lowest in each State) as reported by the USDA NASS, resulting in a 3-year average for Alabama that fell below the required amount of bushels to retain two seats under the Order (§ 1220.201(e)(2)). Accordingly, no change is made as a result of these comments.

Regulatory Flexibility Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS considered the economic effect of this action on small entities and determined that this final rule would not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

Effective November 20, 2019, the Small Business Administration (SBA) [13 CFR 121.201] published an interim final rule (84 FR 64013) that adjusts the monetary-based size standards for inflation. As a result of this rule, the size classification for soybean producers changed from sales of $750,000 or less to sales of $1,000,000 or less. There are an estimated 515,008 soybean producers and an estimated 10,000 first purchasers who collect the assessment, most of whom would be considered small businesses under the criteria established by SBA.

According to USDA's NASS 2017 Census of Agriculture, the number of operations in the United States with soybean production totaled 303,191.[1] The most recent (2017) Census of Agriculture data show that roughly 2 percent of producers with soybean production, or 35,852 operations, have annual receipts of $1,000,000 or more.[2]

The final rule imposes no new burden on the industry, as it only adjusts representation on the Board to reflect changes in soybean production. This adjustment is required by the Order and results in a decrease in Board membership from 78 to 77. AMS is committed to complying with E-Government Act of 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural

[1] *https://www.nass.usda.gov/AgCensus/index.php.*

[2] *https://quickstats.nass.usda.gov/results/A2ADD567-7CE0-3063-9BAD-CB6C0D073DDA.*

research, Marketing agreements, Soybeans and soybean products, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, 7 CFR part 1220 is amended as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

■ 1. The authority citation for part 1220 continues to read as follows:

Authority: 7 U.S.C. 6301–6311 and 7 U.S.C. 7401.

■ 2. In § 1220.201, revise paragraph (a) to read as follows:

§ 1220.201 Membership of board.

(a) For the purpose of nominating and appointing producers to the Board, the United States shall be divided into 31 geographic units and the number of Board members from each unit, subject to paragraphs (d) and (e) of this section shall be as follows:

TABLE 1 TO PARAGRAPH (a)

State/unit	Number of members
South Dakota	4
Ohio	4
North Dakota	4
Nebraska	4
Missouri	4
Minnesota	4
Iowa	4
Indiana	4
Illinois	4
Wisconsin	3
Tennessee	3
Mississippi	3
Michigan	3
Kentucky	3
Kansas	3
Arkansas	3
Virginia	2
Pennsylvania	2
North Carolina	2
Maryland	2
Louisiana	2
Alabama	1
Texas	1
South Carolina	1
Oklahoma	1
New York	1
New Jersey	1
Georgia	1
Delaware	1
Unit:	
Eastern Region (Connecticut, Florida, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, West Virginia, District of Columbia, and Puerto Rico)	1
Western Region (Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming)	1

* * * * *

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–24302 Filed 11–5–21; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 124, 125, 126, and 127

RIN 3245–AH27

National Defense Authorization Act of 2020, Definition of Surviving Spouse for Service-Disabled Veteran-Owned Small Businesses and Change to 8(a) Business Development Contracting Thresholds

AGENCY: U.S. Small Business Administration.

ACTION: Direct final rule.

SUMMARY: This rule makes technical changes to regulations issued by the U.S. Small Business Administration (SBA) to conform those regulations to recent statutory changes. First, the rule incorporates a required change to SBA's ownership requirements for small business concerns owned and controlled by service-disabled veterans. The rule adopts changes to the treatment of certain surviving spouses made by the National Defense Authorization Act of 2020. In addition, the rule incorporates changes to the dollar thresholds for certain contracting actions authorized for the 8(a) Business Development (BD) program made by the National Defense Authorization Act of 2020. Finally, the rule adjusts the competitive threshold dollar levels authorized for SBA's contracting programs to changes made to the Federal Acquisition Regulation (FAR) due to inflation.

DATES: This rule is effective on February 7, 2022, without further action, unless significant adverse comment is received by December 8, 2021. If significant adverse comment is received, SBA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by RIN 3245–AH27, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *For mail, paper, disk, or CD–ROM submissions:* Donna Fudge, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416.

• *Hand Delivery/Courier:* Donna Fudge, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416.

SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Donna Fudge, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416, or send an email to *donna.fudge@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Donna Fudge, Procurement Analyst, Office of Policy, Planning and Liaison, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416; *donna.fudge@sba.gov.*

SUPPLEMENTARY INFORMATION: On December 20, 2019, the National Defense Authorization Act for Fiscal Year 2020 (NDAA 2020), Public Law 116–92, 133 Stat. 1198, was signed into law. Section 876 of NDAA 2020 amended section 3 of the Small Business Act, 15 U.S.C. 632. This provision made changes to the treatment of surviving spouses with regard to the program's ownership requirements. The changes require that SBA update its regulations to reflect two new time periods. Specifically, the statute creates a ten-year time period to remain eligible in the case of a surviving spouse of a veteran with a service-connected disability rated as 100 percent disabling or who dies as a result of a service-connected disability, and a three-year time period in the case of a surviving spouse of a veteran with a service-connected disability rated as less than 100 percent disabling who does not die as a result of a service-connected disability. This rule updates 13 CFR 125.12 to reflect these changes. SBA is changing the language in § 125.12(i)(1)(ii) to match the new statutory language. SBA is adding the ten-year time frame in § 125.12(i)(2)(iii). SBA is adding the three-year time frame in § 125.12(i)(2)(iv).

In addition, section 823 of NDAA 2020 changed the threshold for which a justification and approval is needed for Department of Defense (DoD) covered procurements. Section 811 of the NDAA for Fiscal Year 2010, Public Law 111–

84, 123 Stat. 2190, 2405, required the Federal Acquisition Regulations (FAR) to be amended to include a new requirement for a written justification of sole-source 8(a) awards over $20 million. The FAR increased this threshold to $22 million due to inflation on July 2, 2015. 80 FR 38293, 38296. While the section 811 requirement for a justification and approval applied to all civilian and defense agencies, section 823 of NDAA 2020 increased the threshold to $100 million only for the DoD. As such, this rule amends SBA's regulations to increase the justification and approval requirement to $100 million only with respect to DoD 8(a) contracts. In addition, DoD, the General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA) are charged with amending the FAR to adjust statutory acquisition-related thresholds for inflation every five years. On October 2, 2020, DoD, GSA, and NASA published a final rule in the **Federal Register** amending the FAR to implement new inflationary adjustments. 85 FR 62485. As part of that final rule, the $22 million justification and approval threshold authorized by section 811 of NDAA 2010 was increased to $25 million. Thus, in addition to increasing the threshold to $100 million for DoD-related 8(a) procurements, this rule also increases the justification and approval threshold from $22 million to $25 million for all other agencies. This rule amends § 124.502(c)(17) and § 124.506(b)(5) to adjust the justification and approval thresholds accordingly.

In addition to the justification and approval and 8(a) sole source thresholds identified above that were raised in response to the inflationary adjustments made to the FAR, that same FAR rule also adjusted other SBA-related contacting dollar thresholds for inflation. 85 FR 62485. Section 864 of the National Defense Authorization Act of 2021, Public Law 116–283, subsequently amended the Small Business Act to set the 8(a), HUBZone, and WOSB sole source thresholds for manufacturing contracts to $7,000,000. As such, this rule incorporates the FAR changes into SBA's regulations except where section 864 retained a $7 million sole source threshold amount for manufacturing contracts. Specifically, this rule adopts the inflationary adjustments made to the sole source thresholds in the FAR for the 8(a) BD Program (by amending § 124.506(a)(2)(ii) of SBA's regulations), the Service-Disabled Veteran-Owned Small Business Concern Program (by amending § 125.23(b)(1) of SBA's regulations), the Historically Underutilized Business Zone Program (by amending § 126.612(b)(1) and (2) of SBA's regulations), and the Women-Owned Small Business Program (by amending § 127.503(c)(2) and § 127.503(d)(2) of SBA's regulations). SBA is also updating a threshold for its Small Business Subcontracting Program, which is contained in § 125.3(c).

SBA is also making corrections to § 126.200(f) and § 126.700(b)(1). Currently both sections contain an incorrect reference to § 126.5. The correct cross reference should be to § 125.6, and this rule corrects the typographical errors.

Compliance With Executive Orders 12866, 13563, 12988, 13132, 13175, the Congressional Review Act (5 U.S.C. 801–808), the Paperwork Reduction Act (44 U.S.C. Ch. 35), the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Administrative Procedure Act

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this direct final rule does not constitute a significant regulatory action under Executive Order 12866.

Executive Order 13563

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. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 also requires that regulations be based on the open exchange of information and perspectives among state and local officials, affected stakeholders in the private sector, and the public as a whole. SBA has developed this rule in a manner consistent with these requirements. While developing this rule, SBA responded to specific inquiries from government officials and the public regarding the implementation of the statutory required changes.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

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. This direct final rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

SBA has analyzed this direct final rule and has determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Executive Order 13175

This 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.

Congressional Review Act, 5 U.S.C. 801–808

OMB's Office of Information and Regulatory Affairs has determined that this rule is not a major rule under subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), 5 U.S.C. 804(2).

Paperwork Reduction Act, 44 U.S.C. Ch. 35

SBA has determined that this direct final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C., chapter 35.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. Pursuant to the RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis, which describes the impact of the rule on small entities.

However, section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. Within the meaning of RFA, SBA certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities. It does not add any new requirements to SBA's regulations, but merely adjusts specified thresholds to conform to statutory changes and changes made by the FAR.

Administrative Procedure Act—Justification for Direct Final Rule

In general, SBA publishes a rule for public comment before issuing a final rule, in accordance with the Administrative Procedure Act. 5 U.S.C. 553. The Administrative Procedure Act provides an exception to this standard rulemaking process, however, where an agency finds good cause to adopt a rule without prior public participation. 5 U.S.C. 553(b)(3)(B). The good cause requirement is satisfied when prior public participation is impracticable, unnecessary, or contrary to the public interest.

SBA is publishing this rule as a direct final rule because public participation is unnecessary. SBA views this as a non-controversial administrative action because it merely implements a change required by the Small Business Act, as amended by section 876 of NDAA 2020. This rule will be effective on the date shown in the **DATES** section unless SBA receives significant adverse comment on or before the deadline for comments. Significant adverse comments are comments that provide strong justifications why the rule should not be adopted or for changing the rule. SBA does not expect to receive any significant adverse comments because the rule simply mirrors the statutory language contained in section 876 of NDAA 2020, with no extraneous interpretation or other expanded text. The remaining technical changes merely conform SBA regulations with the updated thresholds in the FAR.

If SBA receives significant adverse comment, SBA will publish a notice in the **Federal Register** withdrawing this rule before the effective date. If SBA receives no significant adverse comments, the rule will be effective 90 days after publication without further notice.

List of Subjects

13 CFR Part 124

Administrative practice and procedure, Government procurement, Government property, Small businesses.

13 CFR Part 125

Government contracts, Government procurement, Reporting and recordkeeping requirements, Small businesses, Technical assistance.

13 CFR Part 126

Administrative practice and procedure, Government procurement, Penalties, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 127

Government contracts, Reporting and recordkeeping requirements, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA amends 13 CFR parts 124, 125, 126, and 127 as follows:

PART 124—8(a) BUSINESS DEVELOPMENT/SMALL DISADVANTAGED BUSINESS STATUS DETERMINATIONS

■ 1. The authority citation for part 124 is revised to read as follows:

Authority: 15 U.S.C. 634(b)(6), 636(j), 637(a), 637(d), 644, 42 U.S.C. 9815; and Pub. L. 99–661, 100 Stat. 3816; Sec. 1207, Pub. L. 100–656, 102 Stat. 3853; Pub. L. 101–37, 103 Stat. 70; Pub. L. 101–574, 104 Stat. 2814; Sec. 8021, Pub. L. 108–87, 117 Stat. 1054; and Sec. 330, Pub. L. 116–260.

■ 2. Amend § 124.502 by revising paragraph (c)(17) to read as follows:

§ 124.502 How does an agency offer a procurement to SBA for award through the 8(a) BD program?

* * * * *

(c) * * *

(17) A statement that the necessary justification and approval under the Federal Acquisition Regulation has occurred where a requirement whose estimated contract value exceeds $25,000,000, or $100,000,000 in the case of Department of Defense contracts, is offered to SBA as a sole source requirement on behalf of a specific Participant; and

* * * * *

■ 3. Amend § 124.506 in paragraph (a)(2)(ii) by removing the figure ''$4,000,000'' and adding in its place the figure ''$4,500,000'' and by revising paragraph (b)(5) to read as follows:

§ 124.506 At what dollar threshold must an 8(a) procurement be competed among eligible Participants?

* * * * *

(b) * * *

(5) An agency may not award an 8(a) sole source contract for an amount exceeding $25,000,000, or $100,000,000 for an agency of the Department of Defense, unless the contracting officer justifies the use of a sole source contract in writing and has obtained the necessary approval under the Federal Acquisition Regulation.

* * * * *

PART 125—GOVERNMENT CONTRACTING PROGRAMS

■ 4. The authority citation for part 125 is revised to read as follows:

Authority: 15 U.S.C. 632(p), (q), 634(b)(6), 637, 644, 657b, 657(f), and 657r.

§ 125.3 [Amended]

■ 5. Amend § 125.3 in paragraphs (c)(1) introductory text and (c)(1)(x) by removing the figure ''$700,000'' and adding in its place the figure ''$750,000''.

■ 6. Amend § 125.12 by revising paragraphs (i)(1)(ii) and (i)(2)(iii) and adding paragraph (i)(2)(iv) to read as follows:

§ 125.12 Who does SBA consider to own an SDVO SBC?

* * * * *

(i) * * *

(1) * * *

(ii) Such veteran had a service-connected disability (as defined in section 101(16) of title 38, United States Code); and

* * * * *

(2) * * *

(iii) In the case of a surviving spouse of a veteran with a service-connected disability rated as 100 percent disabling or who dies as a result of a service-connected disability, is 10 years after the date of the death of the veteran; or

(iv) In the case of a surviving spouse of a veteran with a service-connected disability rated as less than 100 percent disabling who does not die as a result of a service-connected disability, is 3 years after the date of the death of the veteran.

§ 125.23 [Amended]

■ 7. Amend § 125.23 in paragraph (b)(1) by removing the figure ''$6,500,000'' and adding in its place the figure ''$7,000,000''.

PART 126—HUBZONE PROGRAM

■ 8. The authority citation for part 126 is revised to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), 644 and 657a; Pub. L. 111–240, 124 Stat. 2504.

§ 126.200 [Amended]

■ 9. Amend § 126.200 in paragraph (f) by removing the reference ''§§ 126.5'' and adding in its place the reference ''§§ 125.6''.

§ 126.612 [Amended]

■ 10. Amend § 126.612 in paragraph (b)(2) by removing the figure ''4,000,000'' and adding in its place the figure ''$4,500,000''.

§ 126.700 [Amended]

■ 11. Amend § 126.700 in paragraph (b)(1) by removing the reference ''§ 126.5'' and adding in its place the reference ''§ 125.6''.

PART 127—WOMEN-OWNED SMALL BUSINESS FEDERAL CONTRACT PROGRAM

■ 12. The authority citation for part 127 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 637(m), 644 and 657r.

§ 127.503 [Amended]

■ 13. Amend § 127.503 in paragraphs (c)(2) and (d)(2) by removing the figures ''$6,500,000'' and ''$4,000,000'' and adding in their place the figures ''$7,000,000'' and ''$4,500,000'', respectively.

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2021–24348 Filed 11–5–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0950; Project Identifier MCAI–2021–01075–T; Amendment 39–21803; AD 2021–23–05]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–18–08, which applied to all Airbus SAS Model A319–171N airplanes; Model A320–271N, –272N, and –273N airplanes; and Model A321–271N, –272N, –271NX, and –272NX airplanes. AD 2021–18–08 required repetitive inspections of the pylon/engine interface rods for damage, and applicable corrective actions, as specified in European Union Aviation Safety Agency (EASA) AD 2021–0177. AD 2021–18–08 also provided for limited installation of affected parts under certain conditions. Since the FAA issued AD 2021–18–08, operators reported that the requirements of EASA AD 2021–0177 were unclear. This AD retains the requirements of AD 2021–18–08, with clarified instructions, as specified in an EASA AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 23, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 23, 2021.

The FAA must receive comments on this AD by December 23, 2021.

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

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

For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0950.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0950; 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 AD, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Sanjay.Ralhan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0950; Project Identifier MCA–2021–01075–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule because of those comments.

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

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax

206–231–3223; email *Sanjay.Ralhan@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 2021–18–08, Amendment 39–21709 (86 FR 48296, August 30, 2021) (AD 2021–18–08), which applied to all Airbus SAS Model A319–171N airplanes; Model A320–271N, –272N, and –273N airplanes; and Model A321–271N, –272N, –271NX, and –272NX airplanes. AD 2021–18–08 required repetitive inspections of the pylon/engine interface rods for damage, and applicable corrective actions, as specified in EASA AD 2021–0177, dated July 23, 2021 (EASA AD 2021–0177). AD 2021–18–08 also provided for limited installation of affected parts under certain conditions. The FAA issued AD 2021–18–08 to address damage that could lead to rupture of the rod-eye ends, which could result in fuel and hydraulic pipe chafing, consequent fuel or hydraulic leakage, and possible fire.

Actions Since AD 2021–18–08 Was Issued

Since the FAA issued AD 2021–18–08, operators reported that the requirements of EASA AD 2021–0177 were unclear.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0177R1, dated September 21, 2021 (EASA AD 2021–0177R1) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A319–171N, A320–271N, A320–272N, A320–273N, A321–271N, A321–272N, A321–271NX, and A321–272NX airplanes. EASA AD 2021–0177R1 revised EASA AD 2021–0177, dated July 23, 2021 (which corresponded to FAA AD 2021–18–08), to clarify the requirements.

This AD was prompted by a report of damage found at the rod-eye ends of two original rods installed to maintain an interface plate between the pylon and nacelle, and the need to clarify certain existing requirements. The FAA is issuing this AD to address damage that could lead to rupture of the rod-eye ends, which could result in fuel and hydraulic pipe chafing, consequent fuel or hydraulic leakage, and possible fire. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0177R1 specifies procedures for repetitive detailed inspections for damage (including hole damage, a crack, or an abnormal deformation) of the left- and right-hand pylon/engine interface rod ends of the rod attachment fittings, and the interface plate and upper support brackets, measurement of the play/gap of the pylon/engine interface upper and lower rod ends, and applicable corrective actions including rod replacement. EASA AD 2021–0177R1 also provides for limited installation of affected parts under certain conditions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Requirements of This AD

This AD requires accomplishing the actions specified in EASA AD 2021–0177R1 described previously, except for any differences identified as exceptions in the regulatory text of this 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, EASA AD 2021–0177R1 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2021–0177R1 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0177R1 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 2021–0177R1. Service information required by EASA AD 2021–0177R1 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0950 after this AD is published.

Interim Action

The FAA considers this AD interim action. If final action is later identified, the FAA might consider further rulemaking then.

FAA's Justification and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because rupture of the rod-eye ends could result in fuel and hydraulic pipe chafing, consequent fuel or hydraulic leakage, and possible fire. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 204 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 6 work-hours × $85 per hour = Up to $510	$0	Up to $510	Up to $104,040.

* Table does not include estimated costs for reporting.

The FAA estimates that it takes about 1 work-hour per product to comply with the initial reporting requirement in this AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the initial inspection results to be $17,340 for U.S. operators, or $85 per product.

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

ESTIMATED COSTS OF ON-CONDITION REPLACEMENTS

Labor cost	Parts cost	Cost per product
8 work-hours × $85 per hour = $680	$0	$680

The FAA estimates that it would take 1 work-hour per product to comply with the on-condition reporting requirement in this AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting subsequent positive inspection results to be $85 per product for U.S. operators.

The FAA has received no definitive data on which to base the cost estimates for the other on-condition actions specified in this AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

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

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

For the reasons discussed above, I certify that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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) 2021–18–08, Amendment 39–21709 (86 FR 48296, August 30, 2021); and

■ b. Adding the following new AD:

2021–23–05 Airbus SAS: Amendment 39–21803; Docket No. FAA–2021–0950; Project Identifier MCAI–2021–01075–T.

(a) Effective Date

This airworthiness directive (AD) is effective November 23, 2021.

(b) Affected ADs

This AD replaces AD 2021–18–08, Amendment 39–21709 (86 FR 48296, August 30, 2021) (AD 2021–18–08).

(c) Applicability

This AD applies to all Airbus SAS Model A319–171N airplanes; Model A320–271N, –272N, and –273N airplanes; and Model A321–271N, –272N, –271NX, and –272NX airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Unsafe Condition

This AD was prompted by a report of damage found at the rod-eye ends of two original rods installed to maintain an interface plate between the pylon and nacelle, and the need to clarify certain existing requirements from AD 2021–18–08. The FAA is issuing this AD to address damage that could lead to rupture of the rod-eye ends, which could result in fuel and hydraulic pipe chafing, consequent fuel or hydraulic leakage, and possible fire.

(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, European Union Aviation Safety Agency (EASA) AD 2021–0177R1, dated September 21, 2021 (EASA AD 2021–0177R1).

(h) Exceptions to EASA AD 2021–0177R1

(1) Where EASA AD 2021–0177R1 refers to ''06 August 2021 [the effective date of the original issue of this AD],'' this AD requires using September 14, 2021 (the effective date of AD 2021–18–08).

(2) Where EASA AD 2021–0177R1 refers to its effective date, this AD requires using the effective date of this AD.

(3) Paragraph (4) of EASA AD 2021–0177R1 specifies to ''contact Airbus for approved instructions and, within the compliance time(s) specified in those instructions, accomplish those instructions accordingly'' as an alternative corrective action if a defect is detected during inspection of an updated rod. As of the effective date of this AD, however, for that alternative, this AD requires repair of the defect before further flight using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) The ''Remarks'' section of EASA AD 2021–0177R1 does not apply to this AD.

(i) Clarification of EASA AD 2021–0177R1

Paragraph (8) of EASA AD 2021–0177R1 allows installation of an affected part if it is serviceable and inspected within 750 flight hours after installation. The Definitions section of EASA AD 2021–0177R1 requires that a serviceable affected part pass an inspection before the next flight after installation. Therefore, this AD allows installation of an affected serviceable part after the effective date of this AD if it is inspected before further flight after installation and 750 flight hours thereafter. All other provisions of paragraph (8) and Note 2 of EASA AD 2021–0177R1 apply to this AD, including the repetitive inspection of that part as required by paragraph (1) or (2) of EASA AD 2021–0177R1.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Sanjay.Ralhan@faa.gov.*

(l) 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.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0177R1, dated September 21, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0177R1, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0950.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). 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.html.*

Issued on October 27, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24447 Filed 11–4–21; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0257; Project Identifier MCAI–2020–00712–E; Amendment 39–21772; AD 2021–21–12]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) BR700–710A2–20 model turbofan engines. This AD was prompted by flight data obtained from airplanes equipped with certain Rockwell Collins avionics and auto-throttle systems that demonstrated significant oscillation of the engine rotor revolution speed during flight. This AD requires initial and repetitive recalculation of the consumed and remaining service life of certain life-limited parts (LLPs). This AD also

requires removal of an LLP prior to its approved life limit or within 90 days after the effective date of this AD, whichever occurs later. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 13, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 13, 2021.

ADDRESSES: For service information identified in this final rule, contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz, 15827 Blankenfelde-Mahlow, Germany; phone: +49 (0) 33 7086–4040; website: *https://www.rolls-royce.com/contact-us.aspx.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0257.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0257; 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 final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain RRD BR700–710A2–20 model turbofan engines. The NPRM published in the **Federal Register** on April 2, 2021 (86 FR 17326). The NPRM was prompted by flight data obtained from airplanes equipped with certain Rockwell Collins avionics and auto-throttle systems that demonstrated significant oscillation of the engine rotor revolution speed during flight. In the NPRM, the FAA proposed to require initial and repetitive recalculation of the consumed and remaining service life of certain LLPs. The NPRM also proposed to require removal of an LLP prior to its approved life limit or within 90 days after the effective date of this AD, whichever occurs later. The FAA is issuing this AD to address the unsafe condition on these products.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2018–0268, dated December 11, 2018 and corrected on February 20, 2019 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> Flight data obtained from aeroplanes equipped with certain Rockwell Collins avionics and auto-throttle system demonstrated significant oscillation of the engine rotor revolution speed during cruise. Analysis indicates that this affects the service life of the affected LLP.
>
> This condition, if not corrected, may lead to failure of an affected LLP, possibly resulting in release of high-energy debris, with consequent damage to, and/or reduced control of, the aeroplane. To address this potentially unsafe condition, RRD issued the NMSB, providing instructions to recalculate the consumed and remaining service life of the affected LLP.
>
> For the reasons described above, this [EASA] AD requires repetitive recalculation of the service life (consumed and remaining) of each affected LLP and, depending on the results, replacement of each affected LLP before exceeding the life limit, taking the re-calculated life consumption into account.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0257.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter, NetJets Aviation (NJA). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Confirm Compliance With Previous Action

NJA asked if they are in compliance with this AD if they performed the required actions using Bombardier Service Bulletin (SB) 700–34–5021 or Bombardier SB 700–34–6021, revisions earlier than Revision 3, dated January 5, 2018, as applicable. NJA reasoned that paragraph (c), Applicability, of the proposed AD references only Revision 3 of Bombardier SB 700–34–5021 and Bombardier SB 700–34–6021 (Bombardier SBs). NJA states that it performed the required actions using Revision 2 of the Bombardier SBs before the effective date of this AD. NJA also referenced language from Revision 3 of the Bombardier SBs that indicates no further action is necessary if operators performed the action using earlier revisions of the Bombardier SBs.

The FAA notes that NJA would be in compliance with the required actions of this AD if they performed those actions using the earlier versions of the Bombardier SBs to meet the requirements of this AD. The FAA updated paragraph (h), Credit for Previous Actions, of this AD to give credit for using earlier revisions of the Bombardier SBs if the actions were performed before the effective date of this AD.

Request To Confirm Compliance for Simultaneous Actions

NJA asked if they would be in compliance with the required actions of this AD, based on paragraph (h), Credit for Previous Actions, if they complied with the Bombardier SBs and RRD Alert Non-Modification Service Bulletin SB–BR700–72–A900584, Revision 2, dated November 22, 2017 (the NMSB), at the same time before the fleet accumulated 500 flight cycles. NJA indicated that the Accomplishment Instructions, paragraphs 3.A.(1) and (2), of the NMSB apply only to the low-pressure compressor (LPC) disk whereas this AD applies to all LLPs.

The FAA notes that NJA would be in compliance with the replacement of the LPC disk required by paragraph (g)(3) of this AD if they performed the action before the effective date of this AD. Paragraph (f) of this AD mandates compliance with this AD within the compliance times specified, unless already done.

Update to Service Information

The FAA determined the need to incorporate the latest service information in this AD. The FAA revised the reference to Bombardier SB 700–34–5021 in paragraph (c) of this AD from Revision 03, dated January 5, 2018, to Revision 04, dated February 11, 2021, or earlier revision, and Bombardier SB 700–34–6021 in paragraph (c) of this AD from Revision 03, dated January 5, 2018, to Revision 04, dated February 11, 2021, or earlier revision. This change does not change the number of affected engines that the FAA estimated in the NPRM and imposes no additional burden on operators who are required to comply with this AD.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed RRD Alert Non-Modification Service Bulletin SB–BR700–72–A900584, Revision 2, dated November 22, 2017. The NMSB describes procedures for amending flight cycle counting requirements for affected LLPs on RRD BR700–710A2–20 model turbofan engines. 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**.

Other Related Service Information

The FAA reviewed Bombardier SB 700–34–5021, Revision 04, dated February 11, 2021, and Bombardier SB 700–34–6021, Revision 04, dated February 11, 2021. These SBs describe procedures for the implementation of the Global Vision Flight Deck Version 5 (V5) software load on Bombardier Inc. Model BD–700–1A11 and BD–700–1A10 airplanes, respectively.

Costs of Compliance

The FAA estimates that this AD affects 284 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Recalculate service life for affected LLPs	20 work-hours × $85 per hour = $85	$0	$1,700	$482,800

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

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

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

2021–21–12 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce Deutschland GmbH, formerly BMW Rolls-Royce GmbH): Amendment 39–21772; Docket No. FAA–2021–0257; Project Identifier MCAI–2020–00712–E.

(a) Effective Date

This airworthiness directive (AD) is effective December 13, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce Deutschland GmbH, formerly BMW Rolls-Royce GmbH) (RRD) BR700–710A2–20 model turbofan engines:

(1) Installed and operated on a Bombardier Model BD–700–1A10 and BD–700–1A11 airplane, with serial number 9381, 9386, 9401, or 9432 to 9786, inclusive, that have not incorporated Bombardier Service Bulletin (SB) 700–34–5021, Revision 04, dated February 11, 2021, or earlier revision, or Bombardier SB 700–34–6021, Revision 04, dated February 11, 2021, or earlier revision, as applicable, referred to after this as a ''pre-mod airplane,'' or

(2) Installed and operated on a pre-mod airplane at any time after January 1, 2017.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by flight data obtained from airplanes equipped with certain Rockwell Collins avionics and auto-throttle systems which demonstrated significant oscillation of the engine rotor revolution speed during flight. The FAA is issuing this AD to prevent failure of an affected life-limited part (LLP). The unsafe condition, if not addressed, could result in uncontained release of high-energy debris, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 90 days after the effective date of this AD, recalculate the consumed and remaining service life of each affected LLP using Accomplishment Instructions, paragraph 3.D., of RRD Alert Non-Modification Service Bulletin (NMSB) SB–BR700–72–A900584, Revision 2, dated November 22, 2017 (the NMSB).

(2) For engines installed and operated on a pre-mod airplane, after performing the initial recalculations required by paragraph (g)(1) of this AD, for each flight, calculate the consumed and remaining service life of each affected LLP using paragraph 3.D. of the Accomplishment Instructions of the NMSB.

(3) Remove each affected LLP prior to exceeding its approved life limit or within 90 days after the effective date of this AD, whichever occurs later.

(h) Credit for Previous Actions

You may take credit for the recalculation of the consumed and remaining service life of each LLP required by paragraph (g)(1) of this AD if the action was performed before the effective date of this AD using RRD Alert NMSB SB–BR700–72–A900584, Revision 1, dated October 5, 2017, or original issue, dated January 31, 2017.

(i) Definition

For the purpose of this AD, an affected LLP is: a low-pressure compressor (LPC) disk, LPC fan blade, fan shaft, low-pressure turbine (LPT) stage 1 disk, LPT stage 2 disk, LPT rotor shaft and annulus filler, high-pressure compressor (HPC) stage 1–6 rotor disk, HPC stage 7–10 rotor disk, curvic ring, high-pressure turbine (HPT) stage 1 disk, and an HPT stage 2 disk.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

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

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2018–0268, dated December 11, 2018, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0257.

(l) 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 the AD specifies otherwise.

(i) Rolls-Royce Deutschland Ltd & Co KG Alert Non-Modification Service Bulletin SB–BR700–72–A900584, Revision 2, dated November 22, 2017.

(ii) [Reserved]

(3) For Rolls-Royce Deutschland service information identified in this AD, contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz, 15827 Blankenfelde-Mahlow, Germany; phone: +49 (0) 33 7086–4040; website: *https://www.rolls-royce.com/contact-us.aspx.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). 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.html.*

Issued on October 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24182 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0503; Project Identifier AD–2021–00163–T; Amendment 39–21769; AD 2021–21–09]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2005–05–18, which applied to certain The Boeing Company Model 737–600, –700, –700C, –800, and –900 series airplanes. AD 2005–05–18 required repetitive inspections for cracking of the webs of the aft pressure bulkhead at a certain body station, and corrective action if necessary. This AD was prompted by cracking found in that inspection area on airplanes not identified in the applicability of AD 2005–05–18. This AD retains the requirements of AD 2005–05–18, revises the applicability to include additional airplanes, and adds an inspection for existing repairs on the newly added airplanes. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 13, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 13, 2021.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0503.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0503; 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 final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Wayne Lockett, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3524; email: *wayne.lockett@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2005–05–18, Amendment 39–14007 (70 FR 12410, March 14, 2005) (AD 2005–05–18). AD 2005–05–18 applied to certain The Boeing Company Model 737–600, –700, –700C, –800, and –900 series airplanes. The NPRM published in the **Federal**

Register on June 30, 2021 (86 FR 34660). The NPRM was prompted by cracking found in an inspection area on airplanes not identified in the applicability of AD 2005–05–18. In the NPRM, the FAA proposed to continue to require repetitive inspections for cracking of the webs of the aft pressure bulkhead at a certain body station, and corrective action if necessary. The NPRM also proposed to require revising the applicability to include additional airplanes, and adding an inspection for existing repairs on the newly added airplanes. The FAA is issuing this AD to address fatigue cracks in the webs of the aft pressure bulkhead, which could result in rapid decompression of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from United Airlines and Jack Kendrick, who supported the NPRM without change.

The FAA received additional comments from two commenters, including Boeing and Aviation Partners Boeing. The following presents the comments received on the NPRM and the FAA's response to each comment.

Effects of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of blended or split scimitar winglets per Supplemental Type Certificate (STC) ST00830SE does not affect compliance with the proposed actions.

The FAA agrees with the commenter that the installation of winglets per STC ST00830SE does not affect the accomplishment of the manufacturer's service instructions. Therefore, the installation of STC ST00830SE does not affect the ability to accomplish the actions required by this AD. Operators of airplanes with these winglets do not need to request a ''change in product'' alternative method of compliance (AMOC) approval as specified in 14 CFR 39.17. The FAA has redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD, and added paragraph (c)(2) to this AD accordingly.

Request To Clarify Service Information Description

Boeing asked that the FAA clarify the language describing the inspection location and reporting requirements in the ''Related Service Information Under 1 CFR 51'' paragraph in the preamble of the proposed AD. Boeing stated that the language should identify the center dome apex location, and also specify reporting of any cracks found.

The FAA agrees with the commenter's request to clarify the inspection location in the ''Related Service Information'' section, due to the vast number of web fasteners located around the bulkhead. The FAA has clarified that language accordingly.

The FAA does not agree with the commenter's request to add reporting language to that section, because the manufacturer did not include a reporting requirement for this particular cracking condition in the service information. Therefore, the FAA has not changed this AD in this regard.

Request To Clarify Language in Actions Since AD 2005–05–18 Was Issued Section

Boeing requested that the FAA clarify the language in the Actions Since AD 2005–05–18 Was Issued section of the proposed AD. Boeing suggested changing the sentence that begins ''During the assembly process on line numbers 1167 through 1755, the fasteners,'' as follows: ''Fasteners on line numbers 1167 through 1755 in the apex dome region are subjected to clamp-up stresses from the assembly process and fatigue cycles during fuselage pressurization.'' Boeing stated that this change is to clarify the meaning of the language used in the proposed AD.

The FAA acknowledges the commenter's request and agrees the proposed wording provides clarity. However, that section is not carried over into this final rule. Therefore, the FAA has not changed this AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021. This service information specifies procedures for a general visual inspection for existing repairs, repetitive detailed and high frequency eddy current (HFEC) inspections for cracks around the web center dome apex fasteners, repetitive low frequency eddy current (LFEC) inspection for cracks around the hidden web lap splice fastener locations, and repair of cracks. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 744 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Detailed, HFEC, and LFEC inspections.	Up to 10 work-hours × $85 per hour = Up to $850 per inspection cycle.	$0	Up to $850 per inspection cycle.	Up to $632,400 per inspection cycle.
General visual inspection (194 airplanes).	1 work-hour × $85 per hour = $85.	0	$85	$16,490.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair	Up to 30 * work-hours × $85 per hour = Up to $2,550	Up to $30,000 *	Up to $32,550.*

* Repair costs will vary depending on size of the repair required.

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

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

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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) 2005–05–18, Amendment 39–14007 (70 FR 12410, March 14, 2005); and

■ b. Adding the following new AD:

2021–21–09 The Boeing Company: Amendment 39–21769; Docket No. FAA–2021–0503; Project Identifier AD–2021–00163–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 13, 2021.

(b) Affected ADs

This AD replaces AD 2005–05–18, Amendment 39–14007 (70 FR 12410, March 14, 2005) (AD 2005–05–18).

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–600, –700, –700C, –800, and –900 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021.

(2) Installation of Supplemental Type Certificate (STC) ST00830SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report of cracks found at several of the fastener rows in the web lap splices at the dome apex of the aft pressure bulkhead, and the determination that airplanes not affected by AD 2005–05–18 are subject to this unsafe condition. The FAA is issuing this AD to address fatigue cracks in the webs of the aft pressure bulkhead, which could result in rapid decompression of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1251 Revision 2, dated January 20, 2021, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021. For Group 1 airplanes, as defined in Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021: Step 3.B.2. of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, is an RC step, and the provisions of paragraphs (j)(5)(i) and (ii) of this AD apply.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, uses the phrase ''the Revision 1 date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair, or doing the alternative inspections and applicable on-condition actions using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

(1) For airplanes having line numbers 1 through 1166 inclusive: This paragraph provides credit for the corresponding actions of Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, that are required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 737–53–1251, dated June 3, 2004, which was incorporated by reference in AD 2005–05–18.

(2) This paragraph provides credit for the corresponding actions of Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, that are required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 737–53A1251, Revision 1, dated September 22, 2020, which is not incorporated by reference in this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your

principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

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

(4) AMOCs approved for AD 2005–05–18 are approved as AMOCs for the corresponding provisions of Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, that are required by paragraph (g) of this AD.

(5) Except as specified by paragraph (h) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(5)(i) and (ii) of this AD apply.

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

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

(k) Related Information

(1) For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3524; email: *wayne.lockett@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (4) of this AD.

(l) 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 the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021.

(ii) [Reserved]

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

(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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). 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.html.*

Issued on October 8, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24225 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA–2021–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsor Address

AGENCY: Food and Drug Administration, (HHS).

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during April, May, and June 2021. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective November 8, 2021.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2021, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* Marketing exclusivity and patent information may be accessed in FDA's publication, ''Approved Animal Drug Products Online (Green Book)'' at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL, MAY, AND JUNE 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 5, 2021	200–697	Accord Healthcare, Inc., 1009 Slater Rd., Suite 210–B, Durham, NC 27703.	Enrofloxacin Injectable Solution 2.27%.	Dogs	Original approval as a generic copy of NADA 140–913.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL, MAY, AND JUNE 2021—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 12, 2021	141–528	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	CREDELIO CAT (lotilaner) Chewable Tablets.	Cats	Supplemental approval for treatment and control of black-legged tick infestations for one month in cats and kittens.	FOI Summary.
April 23, 2021	200–702	Cronus Pharma Specialties India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	Amoxicillin and Clavulanate Potassium Tablets.	Dogs and cats	Original approval as a generic copy of NADA 055–099.	FOI Summary.
April 26, 2021	139–189	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD (fenbendazole) Type C free-choice medicated feed blocks.	Cattle	Supplemental approval providing for a tolerance and tissue withdrawal periods in accordance with a repartitioning of the acceptable daily intake (ADI); and the addition of indications for 4th-stage larval forms of certain endoparasites.	FOI Summary.
May 18, 2021	141–452	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SIMPARICA (sarolaner) Chewables.	Dogs	Supplemental approval for the prevention of *Borrelia burgdorferi* infection as a direct result of killing *Ixodes scapularis* vector ticks.	FOI Summary.
May 26, 2021	140–269	Do	KETOFEN (ketoprofen) Injectable Solution.	Cattle	Supplemental approval for control of pyrexia associated with bovine respiratory disease (BRD) and establishing a tolerance for residues of ketoprofen in edible tissues of cattle.	FOI Summary.
June 1, 2021	141–543	Do	DRAXXIN KP (tulathromycin and ketoprofen) Injectable Solution.	Cattle	Original approval for the treatment of bovine respiratory disease (BRD) and control of pyrexia associated with BRD in certain classes of cattle.	FOI Summary.
June 10, 2021	200–700	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	PARASEDGE Multi for Dogs (imidacloprid and moxidectin) Topical Solution.	Dogs	Original approval as a generic copy of NADA 141–234.	FOI Summary.
June 10, 2021	200–701	Do	PARASEDGE Multi for Cats (imidacloprid and moxidectin) Topical Solution.	Cats	Original approval as a generic copy of NADA 141–254.	FOI Summary.
June 14, 2021	128–620	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD (fenbendazole) Suspension.		Supplemental approval to establish a milk discard time in cattle and a goat tissue tolerance in accordance with repartitioning of the ADI.	FOI Summary.
June 14, 2021	200–704	Felix Pharmaceuticals PVT Ltd., 25–28 North Wall Quay, Dublin, 1, Ireland.	Deracoxib Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–203.	FOI Summary.
June 28, 2021	200–706	Do	Carprofen Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–111.	FOI Summary.

II. Change of Sponsor's Address

Alexion Pharmaceuticals, Inc., 100 College St., New Haven, CT 06510 has informed FDA that it has changed its address to 121 Seaport Blvd., Boston, MA 02210.

Purina Animal Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126–2910 has informed FDA that it has changed its address to 4001 Lexington Ave., North Arden Hills, MN 55126–2910.

III. Technical Amendments

FDA is making the following amendment to improve the accuracy of the animal drug regulations:

- 21 CFR 520.304 is amended to reflect the currently approved strengths of carprofen chewable tablets.
- 21 CFR part 522 is amended to organize sections for injectable pentobarbital drugs by their titles in alphabetic sequence.
- 21 CFR 558.128 is amended to add introductory text identifying the paragraph for medicated cattle feeds containing chlortetracycline.
- 21 CFR 558.355 is amended to add introductory text identifying the paragraph for medicated cattle feeds containing monensin.

IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and

future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), revise the entries for ''Alexion Pharmaceuticals, Inc.'' and ''Purina Animal Nutrition LLC;'' and

■ b. In the table in paragraph (c)(2), revise the entries for ''017800'' and ''069334''.

The revisions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Alexion Pharmaceuticals, Inc., 121 Seaport Blvd., Boston, MA 02210	069334
* * * * * * *	
Purina Animal Nutrition LLC, 4001 Lexington Ave., North Arden Hills, MN 55126–2910	017800
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
017800	Purina Animal Nutrition LLC, 4001 Lexington Ave., North Arden Hills, MN 55126–2910.
* * * * * * *	
069334	Alexion Pharmaceuticals, Inc., 121 Seaport Blvd., Boston, MA 02210.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 4. In § 520.88g, revise paragraph (b)(2) to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium tablets.

* * * * *

(b) * * *

(2) Nos. 026637 and 069043 for use of tablets as in paragraph (c) of this section.

* * * * *

■ 5. In § 520.304, revise paragraph (b)(2) to read as follows:

§ 520.304 Carprofen.

* * * * *

(b) * * *

(2) Nos. 058198 and 086101 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

* * * * *

■ 6. In § 520.538, remove paragraph (c) and redesignate paragraph (d) as new paragraph (c); and revise paragraph (b) to read as follows:

§ 520.538 Deracoxib.

* * * * *

(b) *Sponsors.* See Nos. 013744, 058198, and 086101 in § 510.600(c) of this chapter.

* * * * *

■ 7. In § 520.905a, revise paragraphs (e)(2), (3), and (4) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(2) *Beef and dairy cattle*—(i) *Amount.* Administer orally 2.3 mg/lb of body weight (5 mg/kg).

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*); adult and fourth-stage larvae barberpole worms (*Haemonchus contortus* and *H. placei*); adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

(iii) *Limitations.* Milk taken from cows during treatment and for 48 hours

after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.

(3) *Beef cattle*—(i) *Amount.* Administer orally 4.6 mg/lb of body weight (10 mg/kg).

(ii) *Indications for use.* For the treatment and control of stomach worms (fourth-stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi,* and tapeworms, *Moniezia benedeni.*

(iii) *Limitations.* Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Goats*—(i) *Amount.* Administer orally 2.3 mg/lb of body weight (5 mg/kg).

(ii) *Indications for use.* For the treatment and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta.*

(iii) *Limitations.* Goats must not be slaughtered for human consumption within 6 days following last treatment with this drug product. Because a milk discard time has not been established, do not use in lactating goats.

* * * * *

§ 520.905e [Removed]

■ 8. Remove § 520.905e.

■ 9. In § 520.1286, revise paragraph (c)(2)(ii) to read as follows:

§ 520.1286 Lotilaner.

* * * * *

(c) * * *

(2) * * *

(ii) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 1 month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater; and for the treatment and control of *Ixodes scapularis* (black-legged tick) for 1 month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater.

* * * * *

■ 10. In § 520.2086, in paragraph (c)(2), add a sentence at the end of the paragraph to read as follows:

§ 520.2086 Sarolaner.

* * * * *

(c) * * *

(2) * * * For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 11. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 12. In § 522.812, revise paragraphs (b)(1) and (e)(1)(i) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 016729, 017033, 055529, and 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and

* * * * *

(e) * * *

(1) * * *

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 30 days.

* * * * *

■ 13. Revise § 522.1225 to read as follows:

§ 522.1225 Ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) ketoprofen.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054771 for use as in paragraphs (d)(1) and (d)(2) of this section.

(2) No. 061133 for use as in paragraph (d)(1) of this section.

(c) *Related tolerances.* See § 556.345 of this chapter.

(d) *Conditions of use*—(1) *Horses—(i) Amount.* Administer by intravenous injection 1.0 mg per pound (/lb) of body weight once daily for up to 5 days.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle—(i) Amount.* Administer by subcutaneous injection 3 mg per kilogram (1.36 mg/lb) of body weight once daily for up to 3 days.

(ii) *Indications for use.* For the control of pyrexia associated with bovine respiratory disease (BRD) in beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, and dairy bulls.

(iii) *Limitations.* Not for use in reproducing animals over 1 year of age. Cattle must not be slaughtered for human consumption within 48 hours following last treatment with this drug product. Not for use in female dairy cattle 1 year of age or older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ § 522.1697, 522.1698, and 522.1704 [Redesignated]

■ 14. Redesignate §§ 522.1697, 522.1698, and 522.1704 as §§ 522.1700, 522.1702, and 522.1703.

■ 15. Add § 522.2632 to read as follows:

§ 522.2632 Tulathromycin and ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin and 120 milligrams (mg) ketoprofen.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.345 and 556.745 of this chapter.

(d) *Conditions of use*—(1) *Cattle—(i) Amount.* Administer as a single subcutaneous injection 2.5 mg tulathromycin and 3 mg ketoprofen per kilogram (1.1 mL/100 lb) of body weight.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis,* and control of pyrexia associated with BRD in beef steers, beef heifers, beef calves 2 months of age and older, beef bulls, dairy bulls, and replacement dairy heifers.

(iii) *Limitations.* Not for use in reproducing animals over 1 year of age. Cattle must not be slaughtered for human consumption within 18 days following last treatment with this drug product. Not for use in female dairy cattle 1 year of age or older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been

established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 16. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 17. In § 524.1146, revise paragraphs (b)(1) and (2) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

* * * * *

(b) * * *

(1) Nos. 017030, 058198, and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) Nos. 017030, 058198, and 061651 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 18. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 19. In § 556.275, revise paragraph (c) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(c) *Related conditions of use.* See §§ 520.905a, 520.905b, 520.905c, 520.905d, and 558.258 of this chapter.

■ 20. Add § 556.345 to read as follows:

§ 556.345 Ketoprofen.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of ketoprofen is 5 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for ketoprofen (marker residue) are:

(1) *Cattle.* (i) Kidney (target tissue): 0.36 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See §§ 522.1225 and 522.2632 of this chapter.

■ 21. In § 556.745, revise paragraph (c) to read as follows:

§ 556.745 Tulathromycin.

* * * * *

(c) *Related conditions of use.* See §§ 522.2630 and 522.2632 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 22. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 23. In § 558.128, revise paragraph (e)(4) introductory text to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) *Cattle.* It is used as follows:

* * * * *

■ 24. In § 558.258, revise paragraph (e)(3)(iii) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

(3) * * *

(iii) *Free-choice medicated feeds*—(A) *Proprietary formulas (§ 510.455(e)(2) of this chapter).* The following feeds can be manufactured only per an approved proprietary formula and specifications:

Amount fenbendazole	Indications for use	Limitations	Sponsor
(*1*) 750 mg/lb of protein block (to provide 5 mg/kg body weight (2.27 mg/lb)).	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 16 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(*2*) 750 mg/lb of molasses block (to provide 5 mg/kg body weight (2.27 mg/lb)).	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 11 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061

(B) *Published formulas (§ 510.455(e)(1) of this chapter).* The following feeds can be manufactured only per one of the formulas and specifications published below:

(1) Amount. 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient [1]	Percent	International feed No.
(*i*) Free-choice, dry Type C feed:		

Ingredient [1]	Percent	International feed No.
Salt (sodium chloride)	59.00	6–04–152
Monosodium phosphate	31.16	6–04–288
Dried cane molasses	3.12	4–04–695
Zinc sulfate	0.76	6–05–556
Copper sulfate	0.45	6–01–720
Fenbendazole 20% Type A article	5.51	n/a
(*ii*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6–04–152
Dicalcium phosphate (18.5% P)	32.44	6–00–080
Calcium carbonate (38% Ca)	15.93	6–01–069
Magnesium oxide (56% Mg)	10.14	6–02–756
Zinc sulfate	1.47	6–05–556
Mineral oil	1.00	8–03–123
Dried cane molasses (46% sugars)	0.98	4–04–695
Potassium iodide	0.01	6–03–759
Fenbendazole 20% Type A article	2.10	n/a
(*iii*) Free-choice, liquid Type C feed:		
Cane molasses [2]	80.902	4–13–251
Water	9.36	n/a
Urea solution, 55%	7.05	5–05–707
Phosphoric acid 75% (feed grade)	2.00	6–03–707
Xantham gum	0.20	8–15–818
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

[1] The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds. Formulation modifications require FDA approval prior to marketing. Selenium is not approved for the free-choice formulations described in paragraph (e)(3)(iii) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (see 21 CFR 573.920).

[2] The percentage of cane molasses and water in the formulation may be adjusted as needed in order to bring the brix value of the molasses to the industry standard of 79.5 brix.

(*2*) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(*3*) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

* * * * *

■ 25. In § 558.355, add a heading to paragraph (f)(3) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) *Cattle*—

* * * * *

Dated: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24075 Filed 11–5–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 010–2021]

Privacy Act of 1974; Implementation

AGENCY: United States Department of Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice (DOJ or Department) is finalizing without changes its Privacy Act exemption regulations for the system of records titled, Department of Justice Information Technology, Information System, and Network Activity and Access Records, JUSTICE/DOJ–002, which were published as a notice of proposed rulemaking (NPRM) (July 22, 2021). Specifically, the Department's regulations will exempt the records maintained in JUSTICE/DOJ–002 from one or more provisions of the Privacy Act. The exemptions are necessary to avoid interference with the efforts of DOJ and others to prevent the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems, and to protect information on DOJ classified networks. The Department received no comments during the notice-and-comment period and is finalizing the rule without change.

DATES: This final rule is effective December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Nickolous Ward, DOJ Chief Information Security Officer, (202) 514–3101, 145 N Street NE, Washington, DC 20530.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Information Security Modernization Act of 2014, among other authorities, DOJ is responsible for complying with information security policies and procedures requiring information security protections commensurate with the risk and magnitude of harm resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems. *See, e.g.,* 44 U.S.C. 3554 (2018). Consistent with these requirements, DOJ must ensure that it maintains accurate audit and activity records of the observable occurrences on its information systems and networks (also referred to as ''events'') that are significant and relevant to the security of DOJ information and information systems. These audit and activity records may include, but are not limited to, information that establishes what type of event occurred, when the event occurred, where the event occurred, the

source of the event, the outcome of the event, and the identity of any individuals or subjects associated with the event. Additionally, monitored events—whether detected utilizing information systems maintaining audit and activity records, reported to the Department by information system users, or reported to the Department by the cybersecurity research community and members of the general public conducting good faith vulnerability discovery activities—may constitute occurrences that (1) actually or imminently jeopardize, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitute a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The Department has developed a formal process to track and document these reported ''incidents,'' which may, in limited circumstances, include records of individuals reporting, or otherwise associated with, an actual or suspected event or incident.

In the **Federal Register** of July 14, 2021 (86 FR 37188), the Department modified a Department-wide system of records retitled, ''Department of Justice Information Technology, Information System, and Network Activity and Access Records,'' JUSTICE/DOJ–002. This system of records covers the Department's tracking of all DOJ information technology, DOJ information system, and DOJ network activity and access by users. These records assist Department information security professionals in protecting DOJ information, ensuring the secure operation of DOJ information systems, and tracking and documenting incidents reported to the agency. The revisions to this notice reflect changes in technology, including the increased ability of the Department to link individuals to information technology, information system, or network activity, and to better describe the Department's records linking individuals to reported cybersecurity incidents or their access to certain information technologies, information systems, and networks through the internet or other authorized connections.

The Department received no comments in response to the NPRM for JUSTICE/DOJ–002 (86 FR 38624 (July 22, 2021)), and now finalizes this rule without changes. In this rulemaking, the Department exempts JUSTICE/DOJ–002 from certain provisions of the Privacy Act in order to avoid interference with the responsibilities of the Department to prevent the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems. Additionally, the Department exempts JUSTICE/DOJ–002 from certain provisions of the Privacy Act to protect activity and audit log records on DOJ classified networks.

The Department notes that the name of the system of records which is the subject of this rule was changed from ''Department of Justice Computer Systems Activity and Access Records'' to ''Department of Justice Information Technology, Information System, and Network Activity and Access Records'' in the notice that was published on July 14, 2021. The NPRM, which was published on July 21, 2021, inadvertently referred to the system of records by the previous name. Additionally, the NPRM indicated in one place an exemption from subsection (d), and in another place an exemption from subsections (d)(1)–(4). In an effort to reduce potential confusion, the language in the final rule has been modified to consistently identify the system of records as being exempted from subsections (d)(1)–(4). Further, corrections have been inserted in the final rule in multiple places where the NPRM had used the term ''system,'' although ''system of records'' was clearly intended. Finally, the proposed rule stated that, in determining the relevance and utility of certain exempted information, it would be vetted and matched with other information necessarily and lawfully maintained by the DOJ, external federal agency subscribers, or other entities. Such information need only be maintained lawfully by the DOJ, external federal agency subscribers, or other entities for use in the vetting and matching described. The Department has determined that these changes do not significantly alter the efficacy of the notice that was provided to the public. The Department has made the adjustments in the final rule, which is published herein.

Executive Orders 12866 and 13563—Regulatory Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'' section 1(b), Principles of Regulation, and Executive Order 13563 ''Improving Regulation and Regulatory Review'' section 1(b), General Principles of Regulation.

The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Information and Regulatory Affairs within the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory Flexibility Act

This regulation will only impact Privacy Act-protected records, which are personal and generally do not apply to an individual's entrepreneurial capacity, subject to limited exceptions. Accordingly, the Chief Privacy and Civil Liberties Officer, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132—Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

This regulation will have no implications for Indian Tribal governments. More specifically, it does not have substantial direct effects 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. Therefore, the consultation requirements of Executive Order 13175 do not apply.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000, as adjusted for inflation, or more in any one year, and it will not significantly or uniquely affect small governments.

Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, 5 U.S.C. 801 *et seq.,* requires the Department to comply with small entity requests for information and advice about compliance with statutes and regulations within the Department's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT** section, above. Persons can obtain further information regarding SBREFA on the Small Business Administration's web page at *https://www.sba.gov/advocacy.* This rule is not a major rule as defined by 5 U.S.C. 804 of the Congressional Review Act.

Paperwork Reduction Act

This rule imposes no information collection or recordkeeping requirements.

List of Subjects in 28 CFR Part 16

Administrative practices and procedures, Courts, Freedom of information, Privacy.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 2940–2008, the Department of Justice amends 28 CFR part 16 as follows:

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

Subpart E—Exemption of Records Systems Under the Privacy Act

■ 2. Add § 16.138 to read as follows:

§ 16.138 Exemption of the Department of Justice Information Technology, Information System, and Network Activity and Access Records, JUSTICE/DOJ–002.

(a) The Department of Justice Information Technology, Information System, and Network Activity and Access Records (JUSTICE/DOJ–002) system of records is exempted from subsections (c)(3); (d)(1), (2), (3) and (4); (e)(1), (e)(4)(G), (H), and (I); and (f) of the Privacy Act of 1974, as amended. The exemptions in this paragraph (a) apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(k)(1) or (k)(2). The applicable exemption may be waived by the DOJ in its sole discretion where DOJ determines compliance with the exempted provisions of the Act would not interfere with or adversely affect the purpose of this system of records to ensure that the Department can track information system access and implement information security protections commensurate with the risk and magnitude of harm that could result from the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and DOJ information systems.

(b) Exemptions from the particular subsections listed in paragraph (a) of this section are justified for the following reasons:

(1) From subsection (c)(3), the requirement that an accounting be made available to the named subject of a record, because this system of records is exempt from the access provisions of subsection (d). Also, because making available to a record subject the accounting of disclosures of records concerning the subject would specifically reveal investigative interests in the records by the DOJ or other entities that are recipients of the disclosures. Revealing this information could compromise sensitive information classified in the interest of national security, or interfere with the overall law enforcement process by revealing a pending sensitive cybersecurity investigation. Revealing this information could also permit the record subject to obtain valuable insight concerning the information obtained during any investigation and to take measures to impede the investigation, *e.g.,* destroy evidence or alter techniques to evade discovery.

(2) From subsection (d)(1), (2), (3) and (4), (e)(4)(G) and (H), and (f) because these provisions concern individual access to and amendment of records, compliance with which regarding certain law enforcement and classified records could alert the subject of an authorized law enforcement activity about that particular activity and the interest of the DOJ and/or other law enforcement or intelligence agencies. Providing access could compromise information classified to protect national security, or reveal sensitive cybersecurity investigative techniques; provide information that would allow a subject to avoid detection; or constitute a potential danger to the health or safety of law enforcement personnel or confidential sources.

(3) From subsection (e)(1) because it is not always possible to know in advance what information is relevant and necessary for law enforcement and intelligence purposes. The relevance and utility of certain information that may have a nexus to cybersecurity threats may not always be fully evident until and unless it is vetted and matched with other information lawfully maintained by the DOJ or other entities.

(4) From subsection (e)(4)(I), to the extent that this subsection is interpreted to require more detail regarding the record sources in this system than has been published in the **Federal Register**. Should the subsection be so interpreted, exemption from this provision is necessary to protect the sources of law enforcement and intelligence information. Further, greater specificity of sources of properly classified records could compromise national security.

Dated: October 26, 2021.

Peter A. Winn,

Acting Chief Privacy and Civil Liberties Officer, United States Department of Justice.

[FR Doc. 2021–24315 Filed 11–5–21; 8:45 am]

BILLING CODE 4410–NW–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 011–2021]

Privacy Act of 1974; Implementation

AGENCY: Justice Management Division, United States Department of Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice (DOJ or Department) is finalizing without changes its Privacy Act exemption regulations for the system of records titled, Security Monitoring and Analytics Service Records, JUSTICE/JMD–026, which were published as a notice of proposed rulemaking (NPRM) on July 30, 3021. Specifically, the Department's regulations will exempt the records maintained in JUSTICE/JMD–026 from one or more provisions of the Privacy Act. The exemptions are necessary to avoid interference with efforts to prevent the unauthorized access, use, disclosure, disruption, modification, or destruction of information, information systems, and networks of DOJ and external Federal agency subscribers. The Department received two comments on the NPRM, neither of which impact the Department's decision to proceed with issuing this final rule.

DATES: This final rule is effective December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Nickolous Ward, DOJ Chief Information Security Officer, (202) 514–3101, 145 N Street NE, Washington, DC 20530.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Information Security Modernization Act of 2014, among other authorities, agencies are responsible for complying with information security policies and procedures requiring information security protections commensurate with the risk and magnitude of harm resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems. *See, e.g.,* 44 U.S.C. 3554 (2018). Executive Order 13800, Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure (May 2017), directs agency heads to show preference in their procurement for shared information technology (IT) services, to the extent permitted by law, including email, cloud, and cybersecurity services. Office of Management and Budget (OMB) Memorandum M–19–16, Centralized Mission Support Capabilities for the Federal Government (April 26, 2019), establishes the framework for implementing the ''Sharing Quality Services'' across agencies. The Economy Act of 1932, as amended, 31 U.S.C. 1535, authorizes agencies to enter into agreements to obtain supplies or services from another agency. Consistent with these authorities, the Justice Management Division (JMD), Office of the Chief Information Officer (OCIO), Cybersecurity Services Staff (CSS), developed the Security Monitoring and Analytics Service (SMAS) system to provide DOJ-managed information technology service offerings to other Federal agencies wishing to leverage DOJ's cybersecurity services, referred to as ''external federal agency subscribers.'' This system provides external Federal agency subscribers with the technical capability to protect their data from malicious or accidental threats using a DOJ-managed system. In the **Federal Register** of July 30, 2021 (86 FR 41089), JMD published a notice of a new system of records titled, ''Security Monitoring and Analytics Service Records,'' JUSTICE/JMD–026, to provide the public notice of the records maintained by DOJ while implementing SMAS.

In this rulemaking, the Department exempts JUSTICE/JMD–026 from certain provisions of the Privacy Act in order to avoid interference with the responsibilities of the Department to prevent the unauthorized access, use, disclosure, disruption, modification, or destruction of external Federal agency subscribers' information and information systems. Additionally, the Department exempts JUSTICE/JMD–026 from certain provisions to assist DOJ and external Federal agency subscribers with protecting such data and ensuring the secure operation of information systems.

The Department received two anonymous comments during the notice-and-comment period. One comment expressed general support for the Department's work to address cybersecurity threats to the government through the implementation of JUSTICE/JMD–026. The second comment broadly questioned whether the proposed exemption would impact in any way the public's ability to access information maintained in the system of records or otherwise reduce the level of transparency required to maintain the public's trust in the Department. As noted in the rule, any restrictions on individual access are based on an articulated need to protect sensitive or law enforcement information. The Privacy Act was drafted to allow agencies to appropriately restrict the public's access to records maintained in a system of records when doing so could potentially reveal sensitive or law enforcement information. When working to ensure cybersecurity, the Department must balance the needs of ensuring transparency and public access with a duty to protect sensitive or law enforcement information that may reveal sources and methods or otherwise compromise law enforcement equities. Accordingly, the Department is proceeding with issuing this final rule without change.

In reviewing the proposed rule (86 FR 40972, July 30, 2021) for publication, the Department identified a minor typographical error in the name and number of the identified system of records proposed to be exempted. Additionally, the proposed rule indicated in one place an exemption from subsection (d), and in another place an exemption from subsections (d)(1)–(4). In an effort to reduce potential confusion, the language in the final rule has been modified to consistently identify the system of records as being exempted from subsections (d)(1)–(4). Further, corrections have been inserted in the final rule in multiple places where the proposed rule had used the term ''system,'' although ''system of records'' was clearly intended. Finally, the proposed rule stated that, in determining the relevance and utility of certain exempted information, it would be vetted and matched with other information necessarily and lawfully maintained by the DOJ, external Federal agency subscribers, or other entities. Such information need only be maintained lawfully by the DOJ, external Federal agency subscribers, or other entities for use in the vetting and matching described. The Department has determined that these changes do not significantly alter the efficacy of the notice that was provided to the public. The Department has made the adjustments in the final rule, which is published herein.

Executive Orders 12866 and 13563–Regulatory Review

In accordance with 5 U.S.C. 552a(j) and 552a(k), this regulation is subject to formal rulemaking procedures by giving interested persons an opportunity to participate in the rulemaking process ''through submission of written data, views, or arguments,'' pursuant to 5 U.S.C. 553. This regulation will promulgate certain Privacy Act exemptions for a DOJ system of records titled, ''Security Monitoring and Analytics Service Records,'' JUSTICE/JMD–026. This regulation does not raise novel legal or policy issues, nor does it adversely affect the economy, the budgetary impact of entitlements, grants, user fees, loan programs, or the rights and obligations of recipients thereof in a material way. The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Information and Regulatory Affairs within the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory Flexibility Act

This regulation will only impact Privacy Act-protected records, which are personal and generally do not apply to an individual's entrepreneurial capacity, subject to limited exceptions. Accordingly, the Chief Privacy and Civil Liberties Officer, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, 5 U.S.C. 801 *et seq.,* requires the Department to comply with small entity requests for information and advice

about compliance with statutes and regulations within the Department's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT** section, above. Persons can obtain further information regarding SBREFA on the Small Business Administration's web page at *https://www.sba.gov/advocacy.* This regulation is not a major rule as defined by 5 U.S.C. 804 of the Congressional Review Act.

Executive Order 13132—Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

This regulation will have no implications for Indian Tribal governments. More specifically, it does not have substantial direct effects 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. Therefore, the consultation requirements of Executive Order 13175 do not apply.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000, as adjusted for inflation, or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by 5 U.S.C. 804 of the Congressional Review Act.

Paperwork Reduction Act

This rule imposes no information collection or recordkeeping requirements.

List of Subjects in 28 CFR Part 16

Administrative practices and procedures, Courts, Freedom of information, Privacy.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 2940–2008, the Department of Justice amends 28 CFR part 16 as follows:

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

Subpart E—Exemption of Records Systems Under the Privacy Act

■ 2. Amend § 16.76 by adding paragraphs (e) and (f) to read as follows:

§ 16.76 Exemption of Justice Management Division.

* * * * *

(e) The following system of records is exempted from 5 U.S.C. 552a(c)(3); (d)(1)–(4); (e)(1), (e)(4)(G), (H), and (I); and (f): Department of Justice Security Monitoring and Analytics Service Records (JUSTICE/JMD–026). The exemptions in this paragraph (e) apply only to the extent that information in this system of records is subject to exemption pursuant to 5 U.S.C. 552a(k)(2). Where DOJ determines compliance would not appear to interfere with or adversely affect the purpose of this system of records to ensure that the Department can track information system access and implement information security protections commensurate with the risk and magnitude of harm that could result from the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems, the applicable exemption may be waived by the DOJ in its sole discretion.

(f) Exemptions from the particular subsections listed in paragraph (e) of this section are justified for the following reasons:

(1) From subsection (c)(3), the requirement that an accounting be made available to the named subject of a record, because this system of records is exempt from the access provisions of subsection (d). Also, because making available to a record subject the accounting of disclosures of records concerning the subject would specifically reveal investigative interests in the records by the DOJ, external Federal agency subscribers, or other entities that are recipients of the disclosures. Revealing this information could compromise sensitive information or interfere with the overall law enforcement process by revealing a pending sensitive cybersecurity investigation. Revealing this information could also permit the record subject to obtain valuable insight concerning the information obtained during any investigation and to take measures to impede the investigation, *e.g.,* destroy evidence or alter techniques to evade discovery.

(2) From subsection (d)(1), (2), (3) and (4), (e)(4)(G) and (H), and (f) because these provisions concern individual access to and amendment of certain law enforcement and sensitive records, compliance of which could alert the subject of an authorized law enforcement activity about that particular activity and the interest of the DOJ, external Federal agency subscribers, and/or other entities that are recipients of the disclosure. Providing access could compromise sensitive information or reveal sensitive cybersecurity investigative techniques; provide information that would allow a subject to avoid detection; or constitute a potential danger to the health or safety of law enforcement personnel or confidential sources.

(3) From subsection (e)(1) because it is not always possible to know in advance what information is relevant and necessary for law enforcement purposes. The relevance and utility of certain information that may have a nexus to cybersecurity threats may not always be fully evident until and unless it is vetted and matched with other information lawfully maintained by the DOJ, external Federal agency subscribers, or other entities.

(4) From subsection (e)(4)(I), to the extent that this subsection is interpreted to require more detail regarding the record sources in this system of records than has been published in the **Federal Register**. Should the subsection be so interpreted, exemption from this provision is necessary to protect the sources of law enforcement information.

Dated: October 26, 2021.

Peter A. Winn,

Acting Chief Privacy and Civil Liberties Officer, United States Department of Justice.

[FR Doc. 2021–24316 Filed 11–5–21; 8:45 am]

BILLING CODE 4410–NW–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2020–0332]

RIN 1625–AA08

Special Local Regulations; Recurring Marine Events Within the Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its special local regulations established for recurring marine events that take place within the Fifth Coast Guard District area of responsibility. The Coast Guard has periodically updated this regulation to account for changes in these marine events. Through this final rule, the current list of recurring marine events requiring special local regulations is updated with revisions, additional events, and the removal of events that no longer take place in the Fifth Coast Guard District area of responsibility. When these special local regulations are enforced, certain restrictions are placed on marine traffic in specified areas to promote safety on the water around marine events.

DATES: This rule is effective December 8, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0332 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ethan Coble, Fifth Coast Guard District Office of Waterways Management, U.S. Coast Guard; telephone (757) 398–7745, email *Ethan.J.Coble@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

APA Administrative Procedure Act
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
MFR Memorandum for Record
NPRM Notice of proposed rulemaking
PATCOM Patrol Commander
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard regularly updates the regulations for recurring special local regulations within the Fifth Coast Guard District listed in 33 CFR 100.501, and its respective tables. These recurring special local regulations are for marine events that take place either on or over the navigable waters of the Fifth Coast Guard District as defined at 33 CFR 3.25. These regulations were last amended June 13, 2017 (81 FR 81005). Since then, Marine Events within the Fifth US Coast Guard District have been newly created or changed in a way that varies from their description in this regulation. In response, on June 03, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulations; Recurring Marine Events and within the Fifth Coast Guard District (86 FR 29711). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to special local regulations and recurring marine events. The comment period ended on July 6, 2021, and we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Secretary has delegated ports and waterways authority, with certain reservations not applicable here, to the Commandant via DHS Delegation No. 00170.1(II)(70), Revision No. 01.2. The Commandant has further delegated these authorities within the Coast Guard as described in 33 CFR 1.05–1 and 6.04–6. The Coast Guard has determined that the events listed in this rule could pose a risk to participants or waterway users if normal vessel traffic were to interfere with the event. Possible hazards include risks of participant injury or death resulting from near or actual contact with non-participant vessels traversing through the regulated areas. In order to protect the safety of all waterway users, including event participants and spectators, this rule establishes special local regulations for the time and location of each marine event. This rule prevents vessels from entering, transiting, mooring or anchoring within areas specifically designated as regulated areas during the periods of enforcement, unless authorized by the Captain of the Port (COTP), or designated Event Patrol Commander.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published June 3, 2021. We made no changes to the regulatory text as it was proposed in our NPRM. The following discussion explains the changes made to the CFR by this rule.

A. Changes To Improve Clarity and Reflect Current Coast Guard Marine Event Policies

We have made several stylistic and formatting changes to update 33 CFR 100.501, and associated tables, to provide greater clarity and remove potential ambiguities. We have also made revisions to reflect current Coast Guard marine event policy. The following is a summary of changes from the current regulatory text:

- Plain language edits, such as switching from passive to active voice and more clearly stating the enforcement period for each event.
- Writing regulatory requirements and definitions in the singular rather than the plural, where appropriate.
- Listing definitions and the events by COTP Zone in alphabetical order.
- Reformatting the table entries so they all are similar.
- Separating the special local regulations for each COTP Zone into their own tables.
- Amending the name and location for Sector Virginia to Portsmouth, VA (where the command center is located), and updating the phone number for Sector North Carolina.

Additionally, we consolidated all defined terms into a single paragraph, 33 CFR 100.501(b), and listed them in alphabetical order. Currently the defined terms ''buffer area'', ''race area'', and ''spectator area'' appear in the regulatory requirements paragraph 33 CFR 100.5014(c) rather than with the definitions. These definitions have been moved to the definition section and put into alphabetical order. Regulatory requirements for these areas will remain in the regulatory requirements portion of the regulation.

We changed the defined term of ''buffer area'' to ''buffer zone'' to comport with the more common usage. The definition is revised to reflect that it may sometimes be appropriate to utilize a buffer zone at the event if there is not a spectator area within the regulated area.

We changed the defined term ''Coast Guard Patrol Commander'' to ''Event Patrol Commander or Event PATCOM'' in alignment with updated local policy. The underlying associated definition

remains the same: A Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on their behalf.

We changed the defined term of ''official patrol'' to ''official patrol vessel or official patrol'' in alignment with updated local policy. The text of the definition remains unchanged except for some additional language to allow the Event PATCOM to be augmented by local, state, or federal officials authorized to act in support of the Coast Guard in accordance with local agreements. This revision enhances the resources available to the COTP to ensure the safety and security of the public during these events.

We removed the defined term, ''spectator'', and added definitions for ''participant'' and ''non-participant''. This wording change better reflects who is actually present in and near regulated areas and how the Coast Guard regulates their activities.

B. Delegation of Authority for Determination of Requirement for a Marine Patrol

We amended current paragraph (b) and (c) in the final text, delegating authority to the local COTP to determine when a marine patrol is required. This delegation of authority from the District Commander provides the local operational commander with the ability to manage and maintain safety and security for events within their area of responsibility. We have also updated the text to allow for other government agencies to provide safety zone enforcement when working under local agreements and added the term Event Patrol Commander (Event PATCOM). Collectively, these changes enable the local Captain of the Port to retain operational control and incorporate risk based decision making to the event. Finally, a paragraph has been added giving authority to the COTP, COTPR, or Event PATCOM to postpone or cancel the event to ensure the safety of the event and the public.

C. Updates to Recurring Events Table 33 CFR 100.501

This rule adds 7 new special local regulations for recurring marine events, revises 12 previously established regulations for recurring marine events, and removes 14 recurring events listed in 33 CFR 100.501 for the reasons provided in the table. The revised events and the new events are required to comply with the requirements in 33 CFR 100.501.

TABLE 1—EVENTS ADDED TO 33 CFR 100.501

USCG sector	Event	Regulated area (coordinates in regulatory text)	Enforcement period *	Sponsor
Sector Maryland-National Capital Region—COTP Zone.	Flying Point Park Outboard Regatta.	Bush River and Otter Point Creek, MD.	One weekend (a consecutive Saturday and Sunday) in May.	Carolina Virginia Racing Association. TCR Event Management.
	Maryland Freedom Swim	Choptank River, MD	1. The 2nd Saturday or Sunday in May; or 2. The 3rd Saturday or Sunday in May; or 3. The 4th Saturday or Sunday in May; or 4. The last Saturday or Sunday in May.	
	Oxford Funathlon Swim ..	Tred Avon River, MD	1. The 1st Saturday or Sunday in June; or 2. The 2nd Saturday or Sunday in June; or 3. The 3rd Saturday or Sunday in June.	Charcot Marie Tooth Association and Therapies for Inherited Neuropathies.
	Thunder on the Choptank	Choptank River and Hambrooks Bay, MD.	1. The 3rd Saturday and Sunday in July; or 2. The 4th Saturday and Sunday in July; or 3. the last Saturday and Sunday in July.	Kent Narrows Racing Association.
	Washington, DC Sharkfest Swim.	Upper Potomac River, MD.	1. The 3rd Saturday or Sunday in June; or 2. The 4th Saturday or Sunday in June; or 3. the last Saturday or Sunday in June	Enviro-Sports Productions Inc.
Sector Virginia—COTP Zone.	Something in the Water ..	North Atlantic Ocean, Virginia Beach, VA.	The last Friday, Saturday, and Sunday in April.	Redrock Entertainment Services.
Sector North Carolina—COTP Zone.	Roanoke River Races	Roanoke River, Plymouth, NC.	1.The 1st Saturday and Sunday in August; or 2. The 2nd Saturday and Sunday in August; or 3. The 3rd Saturday and Sunday in August; or 4. The 4th Saturday and Sunday in August; or 5. The 2nd Saturday and Sunday in October; or 6. The 3rd Saturday and Sunday in October; or 7. The 4th Saturday and Sunday in October; or 8. The last Saturday and Sunday in October	Virginia Outlaw Drag Boat Association (VODBA).

* The enforcement period for each of the listed special local regulations is subject to change in accordance with 33 CFR 100.501(f).

TABLE 2—SUBSTANTIVE CHANGES TO EXISTING RECURRING SPECIAL LOCAL REGULATIONS IN 33 CFR 100.501

USCG sector	Event	Location	Revision	Reason for change
Sector Delaware Bay—COTP zone.	Point Pleasant OPA/NJ Offshore Grand Prix.	Atlantic Ocean, Point Pleasant, NJ.	dates and coordinates	Coordinates updated to reflect accurate course location to improve public safety; event date updated.
	Thunder Over the Boardwalk Air show.	Atlantic Ocean, Atlantic City, NJ.	dates	Event date updated.
	Ocean City Air Show	Intracoastal Waterway, Ocean City, NJ.	dates	Event date updated.
	Triathlons in Atlantic City	Intracoastal Waterway, Atlantic City, NJ.	event name/dates and coordinates.	Coordinates updated with new course layout to ensure public safety; event name and date updated.
Maryland-National Capital Region—COTP Zone.	Washington, DC Dragon Boat Festival.	Upper Potomac, DC	dates	Event date updated.
	Bay Bridge Paddle	Chesapeake Bay, Sandy Point Park, MD.	dates and coordinates	Coordinates updated to reflect course layout change; zone increased to improve public safety; event date updated.
	Catholic Charities Dragon Boat Races.	Patapsco River, MD	dates	Event date updated.
	Baltimore Dragon Boat Challenge.	Patuxent River, MD	coordinates	Coordinates updated to reduce excessive size with no impact on public safety.
	Ocean City Grand Prix	North Atlantic Ocean, Ocean City, MD.	dates and coordinates	Coordinates updated with new course layout to ensure public safety; event date updated.
	Cambridge Classic Powerboat Race.	Choptank River and Hambrooks Bay, MD.	dates and coordinates	Regulated area is increased to prevent hazards within the event area and ensure public safety; change includes minor changes to coordinates for buffer and spectator areas; event date updated.
	Southern Maryland Boat Club Summer Regatta and Bash on the Bay Regatta.	Breton Bay, MD	Event name and dates	Coordinates updated with new course layout at sponsor's request; event name and date updated.
	NAS Patuxent River Air Expo.	Patuxent River, MD	dates	Event dates updated.

TABLE 3—SPECIAL LOCAL REGULATIONS REMOVED FROM TABLE TO 33 CFR 100.501

USCG sector	Event	Date(s)	Regulated area	Reason for removal
Sector Delaware Bay—COTP Zone.	Atlantic County Day at the Bay.	June—1st Sunday	Great Egg Harbor Bay, NJ	Event no longer held.
	Annual Escape from Fort Delaware Triathlon.	May–3rd Sunday; September–3rd Saturday.	Delaware River, DE	Event no longer held.
	Westville Parade of Lights	June–last Saturday	Big Timber Creek, NJ	Event no longer held.
	OPA Atlantic City Grand Prix.	June–4th Sunday	Atlantic Ocean, Atlantic City, NJ.	Event no longer held.
	U.S. Holiday celebrations	July–on or about July 4th	Delaware River, Philadelphia, PA.	Removing special local regulated area and deferring to safety zone for this event; removal does not negatively impact public safety.
	New Jersey Offshore Grand Prix.	May–3rd weekend	Atlantic Ocean, NJ	Event no longer held.
	U.S. Holiday Celebrations	October–1st Monday	Delaware River, Philadelphia, PA.	Removing special local regulated area and deferring to safety zone for this event; removal does not negatively impact public safety.
	U.S. Holiday Celebrations	December 31st	Delaware River, Philadelphia, PA.	Removing special local regulated area and deferring to safety zone for this event; removal does not negatively impact public safety.
Sector Maryland-National Capital Region— COTP Zone.	Middle River Dinghy Poker Run.	July–3rd, 4th, or last Saturday or Sunday.	Middle River, MD	Event no longer held.
	Nanticoke River Swim and Triathlon.	May–1st Sunday	Nanticoke Rivers, MD	Removing special local regulations and deferring to navigation safety regulations; removal does not negatively impact public safety.
	Bo Bowman Memorial—Sharptown Regatta.	June–last Saturday and Sunday or July–2nd Saturday or Sunday.	Nanticoke River, MD	Event is held infrequently and thereby removed from this list of recurring marine events.
	Oxford-Bellevue Sharkfest Swim.	May–2nd, 3rd, 4th or last Saturday or Sunday.	Tred Avon River, MD	Event no longer held.
Sector Virginia—COTP Zone.	RRBA Spring Radar Shootout.	June–last Saturday or July–1st Saturday.	Rappahannock River, Layton, VA.	Event no longer held.
	Hampton Bay Days	September–1st Friday, Saturday and Sunday or 2nd Friday, Saturday and Sunday.	Sunset Creek and Hampton River, VA.	Event no longer held.

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 short amount of time that vessels will be restricted from certain parts of the waterway and the small size of these areas that are usually positioned away from high vessel traffic zones. Generally, vessels will not be precluded from getting underway, or mooring at any piers or marinas currently located in the vicinity of the regulated areas. Advance notifications will also be made to the local maritime community by issuance of Local Notice to Mariners, Broadcast Notice to Mariners via VHF–FM marine channel 16, Marine Safety Information or Security Bulletins so mariners can adjust their plans accordingly. Notifications to the public for most events will typically be made by local newspapers, radio and TV stations. The Coast Guard anticipates that these special local regulations will only be enforced one to three times per year.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit through a safety zone may be small entities, for the reasons stated in section IV.A above, this rule will not have a significant economic impact on any vessel owner or operator. These safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: The Coast Guard will ensure that small entities are able to operate in the areas where events are occurring to the extent possible while ensuring the safety of the public. The enforcement period will be short in duration and, in many of the areas, vessels can transit safely around the special local regulation zone. Generally, permission to enter, remain in, or transit through these regulated areas during the enforcement period may be given when deemed safe to do so by the Event PATCOM on scene.

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 implementation of regulations within 33 CFR part 100 that apply to recurring special local regulations for marine events that take place either on or over the navigable waters of the United States. Some events by their nature may introduce potential for adverse impact on the safety or other interest of waterway users or waterfront infrastructure within or close proximity to the event area. It is categorically excluded from further review under paragraph L [61] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A memorandum for record (MFR) 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

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. Revise § 100.501 to read as follows:

§ 100.501 Special Local Regulations; Marine Events Within the Fifth Coast Guard District.

(a) *Applicability.* Paragraphs (a) through (i) of this section apply to the marine events listed in paragraph (i) of this section. These regulations are effective annually, for the duration of each event listed in paragraph (i) of this section. Annual notice of the exact times, and dates if there is a range of possible dates, of the effective period of the regulation with respect to each event, the geographical area, and details concerning the nature of the event and the number of participants and type(s) of vessels involved will be published in Local Notices to Mariners and via Broadcast Notice to Mariners over VHF–FM marine band radio.

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

Buffer zone means a neutral area that surrounds the perimeter of the regulated area or a race area within a regulated area. The buffer zone provides separation between a race area and spectator area, or between the regulated area and other vessels that are operating in the vicinity of the regulated area for marine event. The purpose of a buffer zone is to minimize potential collision conflicts between participants, participants and non-participants, or between participants and non-participants with nearby transiting vessels.

Captain of the Port Representative or *COTP Representative* means a commissioned, warrant, or petty officer of the Coast Guard designated by name by the Captain of the Port to verify an event's compliance with the conditions of its approved permit.

Event Patrol Commander or *Event PATCOM* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the respective Coast Guard Sector—Captain of the Port to enforce these regulations.

Non-participant means a person or a vessel not registered with the event sponsor either as a participant or an official patrol vessel.

Official patrol vessel or *official patrol* means any vessel assigned or approved by the respective Captain of the Port with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign, or any state or local law enforcement vessel approved by the Captain of the Port in accordance with current local agreements.

Participant means any person or vessel registered with the event sponsor as participating in the event or otherwise designated by the event sponsor as having a function tied to the event.

Race area means an area bound by coordinates provided in latitude and longitude within the regulated area, inside of which the actual racing events are held.

Regulated area means an area where special local regulations apply to a specific described waterway to include creeks, sounds, bays, rivers, and oceans. Regulated areas include all navigable waters of a specific body of water described with intent to define boundaries where the Coast Guard enforces special local regulations. Boundaries may be described from shoreline to shoreline, reference bridges or other fixed structures, by points and lines defined by latitude and longitude. All coordinates reference Datum: NAD 1983.

Spectator area means an area bound by coordinates provided in latitude and longitude within the regulated area that outlines the boundary of an area reserved for non-participant vessels watching the event.

(c) *Patrol of the Marine Event.* The respective COTP may assign one or more official patrol vessels, as described in § 100.40, to each regulated event listed in the table. For each event assigned a patrol vessel, an Event PATCOM will be designated to oversee the patrol. The patrol vessel and the Event PATCOM may be contacted on VHF–FM Channel 16. The Event PATCOM may terminate the event, or the operation of any vessel participating in the marine event, at any time if deemed necessary for the protection of life or property.

(d) *Special local regulations*—(1) *Controls on vessel movement.* The Event PATCOM or official patrol vessel may forbid and control the movement of all persons and vessels in the regulated area(s). When hailed or signaled by an official patrol vessel, the person or vessel being hailed must immediately comply with all directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(2) *Directions, instructions, and minimum speed necessary.* (i) The operator of a vessel in the regulated area must stop the vessel immediately when directed to do so by an official patrol vessel and then proceed only as directed.

(ii) A person or vessel must comply with all instructions of the Event PATCOM or official patrol vessel.

(iii) A vessel operator may request permission to enter and transit through a regulated area by contacting the Event PATCOM or official patrol vessel on VHF–FM channel 16. When authorized to transit through the regulated area, the vessel must proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the event area.

(3) *Race area.* Only participants and official patrol vessels are allowed to enter the race area.

(4) *Spectator area.* Non-participants are only allowed inside the regulated area if they remain within a designated spectator area or have authorization from the Event PATCOM or official patrol vessel to transit through the area. A non-participant vessel must be stationary or operate at a safe speed while within the designated spectator area. On scene official patrol vessels or the Event PATCOM will direct non-participant vessels to the spectator area. A non-participant must contact the Event PATCOM or official patrol vessel to request permission to pass through the regulated area. If permission is granted, the non-participant must pass directly through the regulated area at minimum speed necessary to maintain a safe course that minimizes wake and without loitering.

(5) *Regulated area.* Non-participants are only allowed inside the regulated area to pass through or enter and remain within a designated spectator area. A non-participant must contact the Event PATCOM or an official patrol vessel to request permission to either enter the Spectator Area or pass through the regulated area. If permission is granted, the non-participant may enter the spectator area or pass directly through

the regulated area as instructed by the Event PATCOM or official patrol vessel at minimum speed necessary to maintain a safe course that minimizes wake and without loitering.

(6) *Postponement or cancellation.* The respective COTP, or Event PATCOM may postpone or cancel a marine event at any time if, in the COTP's sole discretion, the COTP determines that cancellation is necessary for the protection of life or property.

(e) *Contact information.* Questions about marine events should be addressed to the local Coast Guard Captain of the Port for the area in which the marine event is occurring. Contact information is listed below. For a description of the geographical area of each Coast Guard Sector—Captain of the Port Zone, please see subpart 3.25 of this chapter.

(1) Coast Guard Sector Delaware Bay—Captain of the Port Zone, Philadelphia, Pennsylvania: (215) 271–4940.

(2) Coast Guard Sector Maryland-National Capital Region—Captain of the Port Zone, Baltimore, Maryland: (410) 576–2525.

(3) Coast Guard Sector Virginia—Captain of the Port Zone, Portsmouth, Virginia: (757) 483–8567.

(4) Coast Guard Sector North Carolina—Captain of the Port Zone, Wilmington, North Carolina: (910) 343–3882.

(f) *Application for marine events.* The application requirements of § 100.15 apply to all marine events listed in paragraph (i) of this section. For information on applying for a marine event permit, contact the Captain of the Port for the area in which the marine event will occur, at the phone numbers listed above.

(g) *Enforcement periods.* Each year prior to an event the Coast Guard will announce details concerning the event, including the exact date(s) and time(s) of the enforcement period of the special local regulation and the geographical area, in the Local Notices to Mariners and by Broadcast Notice to Mariners over VHF–FM marine band radio. In the case of inclement weather or other just cause found by the respective COTP, the event may be conducted within 30 days before or after the date(s) listed in paragraph (i) of this section. If the event is held on an alternate date from that listed in paragraph (i) the Coast Guard will publish a notice in the **Federal Register** announcing the exact dates and time of the enforcement period with respect to the special local regulation in addition to announcement in the Local Notices to Mariners and Broadcast Notice to Mariners.

(h) *Regulations for specific marine events in paragraph (i) of this section*—(1) *USNA Blue Angels Air Show, Coast Guard Sector Maryland-National Capital Region—COTP Zone.* Except for an emergency situation, a vessel may not anchor or maintain station within the spectator area without the permission of the COTP Maryland-National Capital Region or designated Event PATCOM. The COTP Maryland-National Capital Region has designated this spectator area for commercial small passenger vessel use. This area is closed except for commercial small passenger vessels holding a valid Certificate of Inspection regulated under 46 CFR chapter I, subchapters K and T (46 CFR 114.110, and 175.110). Vessels that meet the requirements of this section may request access to the Severn River spectator area by contacting the City of Annapolis Harbormaster at (410) 263–7973 or email *harbormaster@annapolis.gov* to obtain a vessel spectator area application. Vessel spectator area applications shall be submitted no later than 10 calendar days prior to the event date. Applicants will be notified by the COTP Maryland-National Capital Region or COTP representative regarding status of applications and further instructions. All vessels shall contact the Event PATCOM on VHF–FM channels 16 or 22A prior to transiting to the spectator area to confirm entry approval. Vessels approved for spectator area access shall follow the instructions issued by the official patrol vessels or the Event PATCOM when entering the regulated area. The regulations for this event will restrict access to some of the anchorage grounds at Annapolis Harbor, MD, specifically Middle Ground Anchorage, South Anchorage, and Naval Anchorage for Small Craft, listed at 33 CFR 110.159(a)(1) through (4).

(2) *Air Show Baltimore, Coast Guard Sector Maryland-National Capital Region—COTP Zone.* Except for an emergency situation, a vessel may not anchor or hold station within the spectator area without the permission of the COTP Maryland-National Capital Region or Event PATCOM. The COTP Maryland-National Capital Region has designated this spectator area for commercial small passenger vessel use. This area is closed except for commercial small passenger vessels holding a valid Certificate of Inspection regulated under 46 CFR chapter I, subchapters K and T (46 CFR 114.110 and 175.110). Vessels that meet the requirements of this section may request access to the Patapsco River spectator area by contacting the Sail Baltimore at (410) 522–7300 or emailing *info@sailbaltimore.org* to obtain a vessel spectator area application. Vessel spectator area applications shall be submitted no later than 10 calendar days prior to the event date. Applicants will be notified by the COTP Maryland-National Capital Region or COTP representative regarding status of applications and further instructions. All vessels shall contact the Event PATCOM on VHF–FM channels 16 or 22A prior to transiting to the spectator area to confirm entry approval. Vessels approved for spectator area access shall follow the instructions issued by on scene official patrol vessels or the Event PATCOM when entering the regulated area. The regulations for this event will restrict access to some of the anchorage grounds listed at 33 CFR 110.158, Baltimore Harbor, MD. Specifically anchorage grounds:

(i) Anchorage No. 1, general anchorage;

(ii) Anchorage No. 2, general anchorage;

(iii) Anchorage No. 3A, general anchorage; and

(iv) Anchorage No. 3B, general anchorage and

(v) Anchorage No. 3C, general anchorage.

(i) *Special Local Regulations—Recurring Events Within the Fifth Coast Guard District by COTP Zone.* All coordinates listed reference Datum NAD 1983. As noted in paragraph (g) of this section, the enforcement period for each of the listed special local regulations is subject to change.

(1) *Coast Guard Sector Delaware Bay—COTP Zone.*

TABLE 1 TO PARAGRAPH (i)(1)

Event	Regulated area	Enforcement period(s) [1]	Sponsor
Ocean City Air Show ..	All navigable waters of the New Jersey Intracoastal Waterway (ICW) bounded by a line connecting the following points; latitude 39°15′57″ N, longitude 074°35′09″ W, thence northeast to latitude 39°16′34″ N, longitude 074°33′54″ W, thence southeast to latitude 39°16′17″ N, longitude 074°33′29″ W, thence southwest to latitude 39°15′40″ N, longitude 074°34′46″ W, thence northwest to point of origin, near Ocean City, NJ.	One Sunday in September.	Ocean City, NJ.
Point Pleasant OPA/ NJ Offshore Grand Prix.	All navigable waters of the Atlantic Ocean in the vicinity of Point Pleasant Beach, NJ bounded by a line connecting the following points: Latitude 40°06′00″ N, longitude 074°01′51″ W, thence east to latitude 40°05′56″ N, longitude 074°01′16″ W, thence southwest to latitude 40°03′34″ N, longitude 074°01′53″ W, thence west to latitude 40°03′39″ N, longitude 74°02′37″ W, thence north parallel to the shoreline to the point of origin.	1. One Saturday and Sunday in May; or 2. One Saturday and Sunday in June.	Offshore Performance Association (OPA) and New Jersey Offshore Racing Association.
Thunder Over the Boardwalk Air show.	The waters of the North Atlantic Ocean, adjacent to Atlantic City, New Jersey, bounded by a line drawn between the following points: From a point along the shoreline at latitude 39°21′31″ N, longitude 074°25′04″ W, thence southeasterly to latitude 39°21′08″ N, longitude 074°24′48″ W, thence southwesterly to latitude 39°20′16″ N, longitude 074°27′17″ W, thence northwesterly to a point along the shoreline at latitude 39°20′44″ N, longitude 074°27′31″ W, thence northeasterly along the shoreline to latitude 39°21′31″ N, longitude 074°25′04″ W.	One consecutive Monday, Tuesday, and Wednesday in August.	Atlantic City Chamber of Commerce.
Triathlons in Atlantic City.	All navigable waters of the New Jersey Intracoastal Waterway (ICW) bounded by a line connecting the following points: Latitude 39°21′27.47″ N, longitude 074°27′10.31″ W, thence northeast to latitude 39°21′33″ N, longitude 074°26′57″ W, thence northwest to latitude 39°21′37″ N, longitude 074°27′03″ W, thence southwest to latitude 39°21′29.88″ N, longitude 074°27′14.31″ W, thence south to latitude 39°21′19″ N, longitude 074°27′22″ W, thence east to latitude 39°21′18.14″ N, longitude 074°27′19.25″ W, thence north to point of origin, near Atlantic City, NJ.	1. One Saturday in August; and 2. One Sunday in September.	Atlantic City, NJ.

[1] As noted, the enforcement dates and times for each of the listed events in this table are subject to change. In the event of a change, or for enforcement periods listed that do not allow a specific date or dates to be determined, the Captain of the Port will provide notice to the public by publishing a Notice of Enforcement in the **Federal Register**, as well as, issuing a Broadcaster Notice to Mariner.

(2) *Coast Guard Sector Maryland-National Capital Region—COTP Zone.*

TABLE 2 TO PARAGRAPH (i)(2)

Event	Regulated area	Enforcement period(s) [1]	Sponsor
Air Show Baltimore	*Regulated area:* All navigable waters of the Patapsco River, within an area bounded by a line connecting position latitude 39°16′00″ N, longitude 076°36′30″ W, thence east to latitude 39°16′00″ N, longitude 076°33′00″ W, thence south to latitude 39°14′30″ N, longitude 076°33′00″ W, thence west to latitude 39°14′30″ N, longitude 076°36′30″ W, thence north to point of origin, located between Port Covington and Seagirt Marine Terminal, Baltimore, MD. *Spectator Area:* All navigable waters of Patapsco River located between the northern boundary defined by a line drawn from the vicinity of North Locust Point Marine Terminal, Pier 1 thence east to Canton Industrial area, Pier 5; the south boundary is defined by a line drawn from vicinity of Whetstone Point thence east to Lazaretto Point. This area is located generally where Northwest Harbor, East Channel joins Patapsco River, Fort McHenry Channel, near Fort McHenry National Monument, Baltimore, MD. This area is bound by a line to the north commencing at position latitude 39°16′01″ N, longitude 076°34′46″ W, thence east to latitude 39°16′01″ N, longitude 076°34′09″ W, and bound by a line to the south commencing at position latitude 39°15′39″ N, longitude 076°35′23″ W, thence east to latitude 39°15′26″ N, longitude 076°34′03″ W. This spectator area is restricted to certain vessels as described in this paragraph (i)(2).	Biennial, even years: 1. The 2nd Thursday in September, following a Friday, Saturday and Sunday; or 2. The Thursday, Friday, Saturday and Sunday before Columbus Day (observed); or 3. The Thursday, Friday, Saturday and Sunday after Columbus Day (observed).	Historic Ships in Baltimore, Inc.
Baltimore Dragon Boat Challenge.	All navigable waters of Patapsco River, Northwest Harbor, in Baltimore, MD, from shoreline to shoreline, within an area bounded on the east by a line drawn along longitude 076°35′00″ W, and bounded on the west by a line drawn along longitude 076°35′47″ W.	1. June 3rd; or 2. June 4th; or 3. The last Saturday or Sunday in June.	Baltimore Dragon Boat Club.
Bay Bridge Paddle	All navigable waters of the Chesapeake Bay, adjacent to the shoreline at Sandy Point State Park and between and adjacent to the spans of the William P. Lane Jr. Memorial Bridges, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline at latitude 39°01′05.23″ N, longitude 076°23′47.93″ W; thence eastward to latitude 39°01′02.08″ N, longitude 076°22′40.24″ W; thence southeastward to eastern shoreline at latitude 38°59′13.70″ N, longitude 076°19′58.40″ W; and bounded to the south by a line drawn parallel and 500 yards south of the south bridge span that originates from the western shoreline at latitude 39°00′17.08″ N, longitude 076°24′28.36″ W; thence southward to latitude 38°59′38.36″ N, longitude 076°23′59.67″ W; thence eastward to latitude 38°59′26.93″ N, longitude 076°23′25.53″ W; thence eastward to the eastern shoreline at latitude 38°58′40.32″ N, longitude 076°20′10.45″ W, located between Sandy Point and Kent Island, MD.	The 1st Saturday or Sunday in June.	ABC Events, Inc.

TABLE 2 TO PARAGRAPH (i)(2)—Continued

Event	Regulated area	Enforcement period(s) [1]	Sponsor
Cambridge Classic Powerboat Race.	*Regulated area:* All navigable waters within Choptank River and Hambrooks Bay bounded by a line connecting the following coordinates: Commencing at the shoreline at Long Wharf Park, Cambridge, MD, at position latitude 38°34′30″ N, longitude 076°04′16″ W; thence east to latitude 38°34′20″ N, longitude 076°03′46″ W; thence northeast across the Choptank River along the Senator Frederick C. Malkus, Jr. (US–50) Memorial Bridge, at mile 15.5, to latitude 38°35′30″ N, longitude 076°02′52″ W; thence west along the shoreline to latitude 38°35′38″ N, longitude 076°03′09″ W; thence north and west along the shoreline to latitude 38°36′42″ N, longitude 076°04′15″ W; thence southwest across the Choptank River to latitude 38°35′31″ N, longitude 076°04′57″ W; thence west along the Hambrooks Bay breakwall to latitude 38°35′33″ N, longitude 076°05′17″ W; thence south and east along the shoreline to and terminating at the point of origin. The following locations are within the regulated area: *Race area:* Located within the navigable waters of Hambrooks Bay and Choptank River, between Hambrooks Bar and Great Marsh Point, MD. *Buffer zone:* All navigable waters within Hambrooks Bay and Choptank River (with the exception of the Race Area designated by the marine event sponsor) bounded to the north by the breakwall and continuing along a line drawn from the east end of breakwall located at latitude 38°35′27.6″ N, longitude 076°04′50.1″ W, thence W. southeast to latitude 38°35′17.7″ N longitude 076°04′29″W, thence south to latitude 38°35′01″ N longitude 076°04′29″ W, thence west to the shoreline at latitude 38°35′01″ N, longitude 076°04′41.3″ W. *Spectator area:* All navigable waters of the Choptank River, eastward and outside of Hambrooks Bay breakwall, thence bounded by a line that commences at latitude 38°35′28″ N, longitude 076°04′50″ W; thence northeast to latitude 38°35′30″ N, longitude 076°04′47″ W; thence southeast to latitude 38°35′23″ N, longitude 076°04′29″ W; thence southwest to latitude 38°35′19″ N, longitude 076°04′31″ W; thence northwest to and terminating at the point of origin.	One weekend (a consecutive Saturday and Sunday) in May.	Cambridge Power Boat Regatta Association.
Catholic Charities Dragon Boat Races.	The navigable waters of the Patapsco River, within the Inner Harbor, from shoreline to shoreline, bounded on the east by a line drawn along longitude 076°36′30″ W, located at Baltimore, MD.	Biennial, even years: 1. The 1st Saturday in September; or 2. The 2nd Saturday in September.	Associated Catholic Charities, Inc.
Chestertown Tea Party Re-enactment.	All navigable waters of the Chester River, within a line connecting the following positions: Commencing at latitude 39°12′27″ N, longitude 076°03′46″ W, thence south to latitude 39°12′19″ N, longitude 076°03′53″ W, thence east to latitude 39°12′16″ N, longitude 076°03′48″ W, thence north to latitude 39°12′25″ N, longitude 076°03′41″ W, thence west to point of origin latitude 39°12′27″ N, longitude 076°03′46″ W, located at Chestertown, MD.	The Saturday before Memorial Day.	Chestertown Tea Party Festival, Inc.
Eastport Yacht Club Lights Parade.	All navigable waters of Spa Creek and the Severn River, shoreline to shoreline, bounded on the east by a line drawn from Triton Light, at latitude 38°58′53.1″ N, longitude 076°28′34.3″ W, thence southwest to Horn Point, at 38°58′20.9″ N, longitude 076°28′27.1″ W, and bounded on the west by a line drawn along 076°30′00″ W, that crosses the western end of Spa Creek, at Annapolis, MD.	The 2nd Saturday or Sunday in December.	Eastport Yacht Club.
Flying Point Park Outboard Regatta.	*Regulated area:* All navigable waters of Bush River and Otter Point Creek, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline of the Bush River at latitude 39°27′15″ N, longitude 076°14′39″ W and thence eastward to the eastern shoreline of the Bush River at latitude 39°27′03″ N, longitude 076°13′57″ W; and bounded to the south by the Amtrak Railroad Bridge, across the Bush River at mile 6.8, between Perryman, MD and Edgewood, MD. The following locations are within the regulated area: *Race area:* The area is bounded by a line commencing at position latitude 39°26′33.1″ N, longitude 076°15′46.8″ W; thence westerly to latitude 39°26′33.1″ N, longitude 076°15′49.3″ W; thence northerly to latitude 39°26′37.1″ N, longitude 076°15′52.4″ W; thence northeasterly to latitude 39°26′40.0″ N, longitude 076°15′52.5″ W; thence easterly to latitude 39°26′45.9″ N, longitude 076°15′32.2″ W; thence southeasterly to latitude 39°26′45.3″ N, longitude 076°15′30.0″ W; thence southerly to latitude 39°26′43.8″ N, longitude 076°15′29.1″ W; thence southerly to latitude 39°26′42.2″ N, longitude 076°15′28.9″ W; thence southwesterly to latitude 39°26′40.8″ N, longitude 076°15′29.3″ W; thence westerly terminating at point of origin. *Buffer zone:* The area surrounds the entire race area and is bounded by a line commencing at the shoreline at Flying Point Park at position latitude 39°26′31.9″ N, longitude 076°15′32.5″ W; thence westerly to latitude 39°26′30.5″ N, longitude 076°15′52.7″ W; thence northerly to latitude 39°26′39.9″ N, longitude 076°16′00.0″ W; thence easterly to latitude 39°26′51.6″ N, longitude 076°15′26.7″ W; thence southerly to latitude 39°26′37.0″ N, longitude 076°15′22.5″ W; thence southerly to latitude 39°26′33.7″ N, longitude 076°15′22.8″ W, located at the shoreline at Flying Point Park. *Spectator area:* The designated spectator area is bounded by a line commencing at position latitude 39°26′39.9″ N, longitude 076°15′23.3″ W; thence east to latitude 39°26′39.6″ N, longitude 076°15′19.4″ W; thence south to latitude 39°26′36.6″ N, longitude 076°15′18.7″ W; thence west to latitude 39°26′37.0″ N, longitude 076°15′22.5″ W; thence north to point of origin.	One weekend (a consecutive Saturday and Sunday) in May.	Carolina Virginia Racing Association.

TABLE 2 TO PARAGRAPH (i)(2)—Continued

Event	Regulated area	Enforcement period(s) [1]	Sponsor
Great Chesapeake Bay Swim, The.	All navigable waters of the Chesapeake Bay between and adjacent to the spans of the William P. Lane Jr. Memorial Bridges from shoreline to shoreline, bounded to the north by a line drawn parallel and 500 yards north of the north bridge span that originates from the western shoreline at latitude 39°00′36.6″ N, longitude 076°23′55″ W, thence eastward to the eastern shoreline at latitude 38°59′14.2″ N, longitude 076°19′57.3″ W; and bounded to the south by a line drawn parallel and 500 yards south of the south bridge span that originates from the western shoreline at latitude 39°00′18.4″ N, longitude 076°24′28.2″ W, thence eastward to the eastern shoreline at latitude 38°58′39.2″ N, longitude 076°20′8.8″ W.	The 2nd Sunday in June.	The Great Chesapeake Bay Swim, Inc.
Maryland Freedom Swim	All navigable waters of the Choptank River, from shoreline to shoreline, within an area bounded on the east by a line drawn from latitude 38°35′14.2″ N, longitude 076°02′33.0″ W, thence south to latitude 38°34′08.3″ N, longitude 076°03′36.2″ W, and bounded on the west by a line drawn from latitude 38°35′32.7″ N, longitude 076°02′58.3″ W, thence south to latitude 38°34′24.7″ N, longitude 076°04′01.3″ W, located at Cambridge, MD.	1. The 2nd Saturday or Sunday in May; or 2. The 3rd Saturday or Sunday in May; or 3. The 4th Saturday or Sunday in May; or 4. The last Saturday or Sunday in May.	TCR Event Management.
MRE Tug of War, The ...	The navigable waters of Spa Creek from shoreline to shoreline, extending 400 feet from either side of a rope spanning Spa Creek from a position at latitude 38°58′36″ N, longitude 076°29′04.7″ W at Annapolis City Dock, thence to a position at latitude 38°58′25″ N, longitude 076°28′52.4″ W, at Eastport, MD shoreline, near the foot of 2nd Street.	1. The last Saturday in October; or 2. The 1st Saturday in November; or 3. The 2nd Saturday in November.	The Maritime Republic of Eastport.
NAS Patuxent River Air Expo.	All navigable waters of lower Patuxent River, near Solomons, MD, located between Fishing Point and base of break wall marking the entrance to East Seaplane Basin at Naval Air Station Patuxent River (adjacent to approach for runway 14), within an area bounded by a line commencing near the shoreline at latitude 38°17′39″ N, longitude 076°25′47″ W, thence northwest to latitude 38°17′47″ N, longitude 076°26′00″ W, thence northeast to latitude 38°18′09″ N, longitude 076°25′40″ W, thence southeast to latitude 38°18′00″ N, longitude 076°25′25″ W, located near the shoreline at U.S. Naval Air Station Patuxent River, MD. All navigable waters of Chesapeake Bay, located approximately 500 yards north of break wall marking entrance to Chesapeake Bay Basin, Naval Air Station Patuxent River (adjacent to approach for runway 32), within an area bounded by a line commencing near the shoreline at latitude 38°16′53.9″ N, longitude 076°23′29.2″ W, thence southeast to latitude 38°16′40″ N, longitude 076°23′05″ W, thence southwest to latitude 38°16′19″ N, longitude 076°23′25″ W, thence northwest to latitude 38°16′30.4″ N, longitude 076°23′44.9″ W, located near the shoreline at U.S. Naval Air Station Patuxent River, MD.	1. The Thursday, Friday, Saturday and Sunday before Memorial Day (observed); or 2. The Thursday, Friday, Saturday and Sunday after Memorial Day (observed); or 3. The Thursday, Friday, Saturday and Sunday before Labor Day (observed); or 4. The Thursday, Friday, Saturday and Sunday after Labor Day (observed).	NAS Patuxent River.
Ocean City Air Show	All navigable waters of the North Atlantic Ocean within an area bounded by the following coordinates: Commencing at a point near the shoreline in vicinity of 33rd Street, Ocean City, MD, latitude 38°21′48.8″ N, longitude 075°04′10″ W, thence eastward to latitude 38°21′32″ N, longitude 075°03′12″ W, thence south to latitude 38°19′22.7″ N, longitude 075°04′09.5″ W, thence west to latitude 38°19′38.5″ N, longitude 075°05′05.4″ W, thence north along the shoreline to point of origin, located adjacent to Ocean City, MD.	1. The 1st consecutive Thursday, Friday, Saturday, and Sunday in June; or 2. The 2nd consecutive Thursday, Friday, Saturday, and Sunday in June; or 3. The 3rd consecutive Thursday, Friday, Saturday, and Sunday in June.	Town of Ocean City, MD.
Ocean City Offshore Grand Prix.	*Regulated area:* All navigable waters of North Atlantic Ocean bounded by the following coordinates: Commencing at a point near the shoreline at position latitude 38°21′42″ N, longitude 075°04′11″ W; thence east to latitude 38°21′33″ N, longitude 075°03′10″ W; thence southwest to latitude 38°19′25″ N, longitude 075°04′02″ W; thence west to the shoreline at latitude 38°19′35″ N, longitude 075°05′02″ W, at Ocean City, MD. The following locations are within the regulated area: *Race area:* The area is bounded by a line commencing at latitude 38°19′46.85″ N, longitude 075°04′43.28″ W, thence east to latitude 38°19′44.23″ N, longitude 075°04′29.89″ W, thence north and parallel to the Ocean City, MD shoreline to latitude 38°21′23.24″ N, longitude 075°03′48.87″ W, thence west to latitude 38°21′25.12″ N, longitude 075°04′02.45″ W, thence south and parallel to the Ocean City, MD shoreline to the point of origin. *Buffer zone:* The area is 500 yards in all directions surrounding the ''Race area'' and is bounded by a line commencing at a point near the shoreline at latitude 38°19′35″ N, longitude 075°05′02″ W, thence east to latitude 38°19′28″ N, longitude 075°04′17″ W, thence north and parallel to Ocean City, MD shoreline to latitude 38°21′35″ N, longitude 075°03′24″ W, thence west to the shoreline at latitude 38°21′42″ N, longitude 075°04′11″ W, thence south along the Ocean City, MD shoreline to the point of origin. *Spectator area:* The area is bounded by a line commencing at latitude 38°19′40″ N, longitude 075°04′12″ W, thence east to latitude 38°19′37″ N, longitude 075°03′59″ W, thence northeast and parallel to the Ocean City, MD shoreline to latitude 38°21′17″ N, longitude 075°03′17″ W, thence west to latitude 38°21′20″ N, longitude 075°03′31″ W, thence southwest and parallel to Ocean City, MD shoreline to the point of origin.	1. The 1st Sunday in May; or 2. The 2nd Sunday in May; or 3. The 2nd Sunday in September; or 4. The 3rd Sunday in September; or 5. The 4th Sunday in September; or 6. The last Sunday in September.	Offshore Powerboat Association.

TABLE 2 TO PARAGRAPH (i)(2)—Continued

Event	Regulated area	Enforcement period(s) [1]	Sponsor
Oxford Funathlon Swim	The navigable waters of the Tred Avon River from shoreline to shoreline, within an area bounded on the east by a line drawn from latitude 38°42′25″ N, longitude 076°10′45″ W, thence south to latitude 38°41′37″ N, longitude 076°10′26″ W, and bounded on the west by a line drawn from latitude 38°41′58″ N, longitude 076°11′04″ W, thence south to latitude 38°41′25″ N, longitude 076°10′49″ W, thence east to latitude 38°41′25″ N, longitude 076°10′30″ W, located between Bellevue, MD, and Oxford, MD.	1. The 1st Saturday or Sunday in June; or 2. The 2nd Saturday or Sunday in June; or 3. The 3rd Saturday or Sunday in June.	Charcot Marie Tooth Association and Therapies for Inherited Neuropathies.
Rock Hall and Waterman's Triathlon Swims.	The navigable waters of Rock Hall Harbor from shoreline to shoreline, bounded by a line drawn from latitude 39°07′58.9″ N, longitude 076°15′02″ W, thence southeast and parallel along the harbor breakwall to latitude 39°07′50.1″ N, longitude 076°14′41.7″ W, located at Rock Hall, MD.	1. The Saturday and Sunday after Memorial Day (observed); and 2. The 1st Saturday and Sunday in October.	Kinetic Multisports, LLC.
Southern Maryland Boat Club Summer and Fall Regattas.	*Regulated area:* All navigable waters of Breton Bay and McIntosh Run, immediately adjacent to Leonardtown, MD shoreline, from shoreline to shoreline, within an area bounded to the east by a line drawn along latitude-38°16′43″ N, and bounded to the west by a line drawn along longitude 076°38′30″ W, located at Leonardtown, MD. The following locations are within the regulated area: *Race area:* The area is bounded by a line commencing at position latitude 38°17′09.78″ N, longitude 076°38′22.71″ W, thence southeast to latitude 38°16′58.62″ N, , longitude 076°37′50.91″ W, thence southwest to latitude 38°16′51.89″ N, longitude 076°37′55.82″ W, thence northwest to latitude 38°17′05.44″ N, longitude 076°38′27.20″ W, thence northeast to point of origin. *Buffer zone:* The area is approximately 125 yards in all directions surrounding the ''Race area'' and is bounded by a line commencing at the shoreline west of Leonardtown Wharf Park at position latitude 38°17′13.80″ N, longitude 076°38′24.72″ W, thence southeast to latitude 38°16′58.61″ N, longitude 076°37′44.29″ W, thence southwest to latitude 38°16′46.35″ N, longitude 076°37′52.54″ W, thence northwest to latitude 38°16′58.78″ N, longitude 076°38′26.63″ W, thence north to latitude 38°17′07.50″ N, longitude 076°38′30.00″ W, thence northeast to point of origin. *Spectator areas:* Northeast Spectator Fleet Area: The area is bounded by a line commencing at position latitude 38°16′59.10″ N, longitude 076°37′45.60″ W, thence northeast to latitude 38°17′01.76″ N, longitude 076°37′43.71″ W, thence southeast to latitude 38°16′59.23″ N, longitude 076°37′37.25″ W, thence southwest to latitude 38°16′53.32″ N, longitude 076°37′40.85″ W, thence northwest to latitude 38°16′55.48″ N, longitude 076°37′46.39″ W, thence northeast to latitude 38°16′58.61″ N, longitude 076°37′44.29″ W, thence northwest to point of origin. *Southeast Spectator Fleet Area:* The area is bounded by a line commencing at Buzzard Point at position latitude 38°16′47.20″ N, longitude 076°37′54.80″ W, thence south to latitude 38°16′43.30″ N, longitude 076°37′55.20″ W, thence east to latitude 38°16′43.20″ N, longitude 076°37′47.80″ W, thence north to latitude 38°16′44.80″ N, longitude 076°37′48.20″ W, thence northwest to point of origin. *South Spectator Fleet Area:* The area is bounded by a line commencing at position latitude 38°16′55.36″ N, longitude 076°38′17.26″ W, thence southeast to latitude 38°16′50.39″ N, longitude 076°38′03.69″ W, thence south to latitude 38°16′48.87″ N, longitude 076°38′03.68″ W, thence northwest to latitude 38°16′53.82″ N, longitude 076°38′17.28″ W, thence north to point of origin.	Summer: 1. July 4th; or 2. The last Saturday and Sunday of July; Fall: 1. The 1st Saturday and Sunday in October; or 2. The 2nd Saturday and Sunday in October.	Southern Maryland Boat Club.
Thunder on the Choptank.	*Regulated area:* All navigable waters within Choptank River and Hambrooks Bay bounded by a line connecting the following coordinates: Commencing at the shoreline at Long Wharf Park, Cambridge, MD, at position latitude 38°34′30″ N, longitude 076°04′16″ W; thence east to latitude 38°34′20″ N, longitude 076°03′46″ W; thence northeast across the Choptank River along the Senator Frederick C. Malkus, Jr. (US–50) Memorial Bridge, at mile 15.5, to latitude 38°35′30″ N, longitude 076°02′52″ W; thence west along the shoreline to latitude 38°35′38″ N, longitude 076°03′09″ W; thence north and west along the shoreline to latitude 38°36′42″ N, longitude 076°04′15″ W; thence southwest across the Choptank River to latitude 38°35′31″ N, longitude 076°04′57″ W; thence west along the Hambrooks Bay breakwall to latitude 38°35′33″ N, longitude 076°05′17″ W; thence south and east along the shoreline to and terminating at the point of origin. The following locations are within the regulated area: *Race Area:* Located within the navigable waters of Hambrooks Bay and Choptank River, between Hambrooks Bar and Great Marsh Point, MD. *Buffer zone:* All navigable waters within Hambrooks Bay and Choptank River (with the exception of the Race Area designated by the marine event sponsor) bound to the north by the breakwall and continuing along a line drawn from the east end of breakwall located at latitude 38°35′27.6″ N, longitude 076°04′50.1″ W; thence southeast to latitude 38°35′17.7″ N, longitude 076°04′29″ W; thence south to latitude 38°35′01″ N, longitude 076°04′29″ W; thence west to the shoreline at latitude 38°35′01″ N, longitude 076°04′41.3″ W. *Spectator area:* All navigable waters of the Choptank River, eastward and outside of Hambrooks Bay breakwall, thence bound by line that commences at latitude 38°35′28″ N, longitude 076°04′50″ W; thence northeast to latitude 38°35′30″ N, longitude 076°04′47″ W; thence southeast to latitude 38°35′23″ N, longitude 076°04′29″ W; thence southwest to latitude 38°35′19″ N, longitude 076°04′31″ W; thence northwest to and terminating at the point of origin.	1. The 3rd Saturday and Sunday in July; or 2. The 4th Saturday and Sunday in July; or 3. The last Saturday and Sunday in July.	Kent Narrows Racing Association.

TABLE 2 TO PARAGRAPH (i)(2)—Continued

Event	Regulated area	Enforcement period(s) [1]	Sponsor
USNA Blue Angels Air Show.	*Regulated area:* All navigable waters of the Severn River, from shoreline to shoreline, bounded to the northwest by a line drawn along the U.S. 50 fixed highway bridge. The regulated area is bounded to the southeast by a line drawn from U.S. Naval Academy Light at latitude 38°58′39.5″ N, longitude 076°28′49″ W, thence southeast to a point 1500 yards ESE of Chinks Point, MD at latitude 38°57′41″ N, longitude 076°27′36″ W, thence northeast to Greenbury Point at latitude 38°58′27.7″ N, longitude 076°27′16.4″ W. The following location is within the regulated area: *Spectator area:* All navigable waters of the Severn River bounded by a line commencing at latitude 38°58′38.2″ N, longitude 076°27′56.9″ W, thence southeast to latitude 38°58′24.9″ N, longitude 076°27′47.6″ W, thence west to latitude 38°58′22.3″ N, longitude 076°27′54.5″ W, thence northwest to latitude 38°58′28.3″ N, longitude 076°28′11″ W, thence east to point of origin. This area is located generally in the center portion of Middle Ground Anchorage, Severn River, MD. This spectator area is restricted to certain vessels as described in paragraph (i)(1) of this section.	The Tuesday and Wednesday before Memorial Day (observed).	U.S. Naval Academy.
USNA Crew Races	All navigable waters of the Severn River, from shoreline to shoreline, bounded to the northwest by a line drawn from the south shoreline at latitude 39°00′58″ N, longitude 076°31′32″ W, thence to the north shoreline at latitude 39°01′11″ N, longitude 076°31′10″ W. The regulated area is bounded to the southeast by a line drawn from U.S. Naval Academy Light at latitude 38°58′39.5″ N, longitude 076°28′49″ W, thence easterly to Carr Point, MD at latitude 38°58′58″ N, longitude 076°27′41″ W.	The 3rd Saturday and Sunday in April; and the 4th Saturday and Sunday in April; and the last Saturday and Sunday in April; and every Saturday and Sunday in May.	U.S. Naval Academy.
USNA Safety at Sea Seminar.	All navigable waters of the Severn River, from shoreline to shoreline, bounded to the northwest by the Naval Academy (SR–450) Bridge and bounded to the southeast by a line drawn from Triton Light at latitude 38°58′53.0″ N, longitude 076°28′34.4″ W, thence easterly to Carr Point, MD at latitude 38°58′58.7″ N, longitude 076°27′38.9″ W.	1. The 4th Saturday in March; or 2. The last Saturday in March; or 3. The 1st Saturday in April.	U.S. Naval Academy.
Washington, DC Dragon Boat Festival.	All navigable waters of the Upper Potomac River, Washington, DC, from shoreline to shoreline, bounded upstream by the Francis Scott Key Bridge and downstream by the Roosevelt Memorial Bridge, located at Georgetown, Washington, DC.	1. The 3rd Saturday and Sunday in May; or 2. The 2nd Saturday and Sunday in June; or 3. The 3rd Saturday and Sunday in June.	Taiwan—U.S. Cultural Association.
Washington's Crossing: Swim Across the Potomac.	All navigable waters of the Potomac River, encompassed by a line connecting the following points, beginning at Jones Point Park, VA, shoreline at latitude 38°47′35″ N, longitude 077°02′22″ W, thence east along the northern extent of the Woodrow Wilson Memorial (I–495/I–95) Bridge, at mile 103.8, to the Rosilie Island shoreline at latitude 38°47′36″ N, longitude 077°01′32″ W, thence south along the Maryland shoreline to latitude 38°46′52″ N, longitude 077°01′13″ W, at National Harbor, MD shoreline, thence west across the Potomac River to the George Washington Memorial Parkway highway overpass and Cameron Run shoreline at latitude 38°47′23″ N, longitude 077°03′03″ W, thence north along the Virginia shoreline to the point of origin.	The 1st Sunday in June.	Wave One Swimming.
Washington DC Sharkfest Swim.	All navigable waters of the Upper Potomac River, within an area bounded by a line connecting the following points: From the Rosilie Island shoreline at latitude 38°47′30.30″ N, longitude 077°01′26.70″ W, thence west to latitude 38°47′30.00″ N, longitude 077°01′37.30″ W, thence south to latitude 38°47′08.20″ N, longitude 077°01′37.30″ W, thence east to latitude 38°47′09.00″ N, longitude 077°01′09.20″ W, thence southeast along the pier to latitude 38°47′06.30″ N, longitude 077°01′02.50″ W, thence north along the shoreline and west along the southern extent of the Woodrow Wilson (I–95/I–495) Memorial Bridge and south and west along the shoreline to the point of origin, located at National Harbor, MD.	1. The 3rd Saturday or Sunday in June; or 2. The 4th Saturday or Sunday in June; or 3. The last Saturday or Sunday in June.	Enviro-Sports Productions Inc.

[1] As noted, the enforcement dates and times for each of the listed events in this table are subject to change. In the event of a change, or for enforcement periods listed that do not allow a specific date or dates to be determined, the Captain of the Port will provide notice to the public by publishing a Notice of Enforcement in the FEDERAL REGISTER, as well as, issuing a Broadcaster Notice to Mariner.

(3) *Coast Guard Sector Virginia—COTP Zone.*

TABLE 3 TO PARAGRAPH (i)(3)

Event	Regulated area	Enforcement [1] period(s)	Sponsor
Blackbeard Festival, Battle of Hampton.	*Regulated area:* The navigable waters of Sunset Creek and Hampton River shoreline to shoreline bounded to the north by the I–64 Bridge over the Hampton River and bounded to the south by a line drawn from Hampton River Channel Light 16 (LL 10945), located at latitude 37°01′03″ N, longitude 076°20′24″ W, thence west across the Hampton River to finger pier at Bluewater Yacht Center, located at latitude 37°01′03″ N, longitude 076°20′28″ W. The following locations are within the regulated area: *Spectator areas: Area A:* Located in the upper reaches of the Hampton River, bounded to the south by a line drawn from the western shoreline at latitude 37°01′46.6″ N, longitude 076°20′21.3″ W, thence east across the river to latitude 37°01′42.6″ N, longitude 076°20′12.3″ W, and bounded to the north by the I–64 Bridge over the Hampton River. The anchorage area will be marked by orange buoys. *Area B:* Located along the eastern side of the Hampton River channel, south of the route 60/143 bridge and Joy's Marina, and adjacent to the shoreline that fronts the Riverside Health Center. Bounded by the shoreline and a line drawn between the following points: latitude 37°01′27.6″ N, longitude 076°20′23.1″ W, thence south to latitude 37°01′22.9″ N, longitude 076°20′26.1″ W. The anchorage area will be marked by orange buoys.	1. Last Friday, Saturday and Sunday in May; or The 1st Friday, Saturday and Sunday in June; and 2. The 3rd Friday, Saturday and Sunday in October; or 4th Friday, Saturday and Sunday in October.	City of Hampton.
Cock Island Race	The navigable waters of the Elizabeth River and its branches from shoreline to shoreline, bounded to the northwest by a line drawn across the Port Norfolk Reach section of the Elizabeth River between the northern corner of the landing at Hospital Point, Portsmouth, VA, latitude 36°50′51.6″ N, longitude 076°18′07.9″ W and the north corner of the City of Norfolk Mooring Pier at the foot of Brooks Avenue located at latitude 36°51′00.3″ N, longitude 076°17′51″ W; bounded on the southwest by a line drawn from the southern corner of the landing at Hospital Point, Portsmouth, VA, at latitude 36°50′50.9″ N, longitude 076°18′07.7″ W, to the northern end of the eastern most pier at the Tidewater Yacht Agency Marina, located at latitude 36°50′33.6″ N, longitude 076°17′54.1″ W; bounded to the south by a line drawn across the Lower Reach of the Southern Branch of the Elizabeth River, between the Portsmouth Lightship Museum located at the foot of London Boulevard, in Portsmouth, VA at latitude 36°50′13.2″ N, longitude 076°17′44.8″ W, and the northwest corner of the Norfolk Shipbuilding & Drydock, Berkley Plant, Pier No. 1, located at latitude 36°50′08.8″ N, longitude 076°17′37.5″ W; and bounded to the southeast by the Berkley Bridge which crosses the Eastern Branch of the Elizabeth River between Berkley at latitude 36°50′21.5″ N, longitude 076°17′14.5″ W, and Norfolk at latitude 36°50′35″ N, longitude 076°17′10″ W.	1. The 2nd Saturday in June; or 2. The 3rd Saturday in June.	Portsmouth Boat Club & City of Portsmouth, VA.
Hampton Cup Regatta ...	*Regulated area:* All navigable waters of Mill Creek, adjacent and north of Fort Monroe, Hampton, VA. The regulated area includes the following areas: *Race area:* All navigable waters within the following boundaries: To the north, a line drawn along latitude 37°01′03″ N, to the east a line drawn along longitude 076°18′30″ W, to the south a line drawn parallel with the Fort Monroe shoreline, and west boundary is parallel with the Route 258—East Mercury Boulevard Bridge—causeway. The following locations are within the regulated area: *Buffer zone A:* All navigable waters bounded by a line connecting the following points: Latitude 37°00′43″ N, longitude 076°18′54″ W, thence north along the causeway to latitude 37°01′03″ N, longitude 076°18′52″ W, thence southwest to latitude 37°01′00″ N, longitude 076°18′54″ W, thence south to Route 143 causeway at latitude 37°00′44″ N, longitude 076°18′58″ W, thence east along the shoreline to point of origin. *Buffer zone B:* All navigable waters bounded by a line connecting the following points: latitude 37°01′08″ N, longitude 076°18′49″ W, thence east to latitude 37°01′08″ N, longitude 076°18′23″ W, thence south to latitude 37°00′33″ N, longitude 076°18′23″ W, thence west to latitude 37°00′33″ N, longitude 076°18′30″ W, thence north to latitude 37°01′03″ N, longitude 076°18′30″ W, thence west to latitude 37°01′03″ N, longitude 076°18′49″ W, thence north to point of origin. *Spectator area:* All navigable waters bounded by a line connecting the following points: latitude 37°01′08″ N, longitude 076°18′23″ W, thence east to latitude 37°01′08″ N, longitude 076°18′14″ W, thence south to latitude 37°00′54″ N, longitude 076°18′14″ W, thence southwest to latitude 37°00′37″ N, longitude 076°18′23″ W, thence north to point of origin.	1. The 1st consecutive Friday, Saturday, and Sunday in August; or 2. the 2nd consecutive Friday, Saturday and Sunday in August; and 3. The 4th Saturday and Sunday in September.	Hampton Cup Regatta Boat Club.
Mattaponi Drag Boat Race.	*Regulated area:* All navigable waters of Mattaponi River immediately adjacent to Rainbow Acres Campground, King and Queen County, VA. The regulated area includes a section of the Mattaponi River approximately three-quarter mile long and bounded in width by each shoreline, bounded to the east by a line that runs parallel along longitude 076°52′43″ W, near the mouth of Mitchell Hill Creek, and bounded to the west by a line that runs parallel along longitude 076°53′41″ W just north of Wakema, VA. The following locations are within the regulated area: *Buffer zone:* The navigable waters of Mattaponi River extending 200 yards outwards from east and west boundary lines described in this section. *Spectator area:* The regulated area cannot accommodate spectator vessels due to limitations posed by shallow water and insufficient waters to provide adequate separation between race course and other vessels. Spectators are encouraged to view the race from points along the adjacent shoreline.	1. The 3rd Saturday and Sunday in June; or 2. The 4th Saturday and Sunday in June.	Mattaponi Volunteer Rescue Squad and Dive Team.

TABLE 3 TO PARAGRAPH (i)(3)—Continued

Event	Regulated area	Enforcement [1] period(s)	Sponsor
Norfolk Harborfest	The navigable waters of the Elizabeth River and its branches from shoreline to shoreline, bounded to the northwest by a line drawn across the Port Norfolk Reach section of the Elizabeth River between the north corner of the landing at Hospital Point, Portsmouth, VA, latitude 36°50′51.6″ N, longitude 076°18′07.9″ W, and the north corner of the City of Norfolk Mooring Pier at the foot of Brooks Avenue located at latitude 36°51′00.3″ N, longitude 076°17′51″ W; bounded on the southwest by a line drawn from the southern corner of the landing at Hospital Point, Portsmouth, VA, at latitude 36°50′50.9″ N, longitude 076°18′07.7″ W, to the northern end of the eastern most pier at the Tidewater Yacht Agency Marina, located at latitude 36°50′33.6″ N, longitude 076°17′54.1″ W; bounded to the south by a line drawn across the Lower Reach of the Southern Branch of the Elizabeth River, between the Portsmouth Lightship Museum located at the foot of London Boulevard, in Portsmouth, VA at latitude 36°50′13.2″ N, longitude 076°17′44.8″ W, and the northwest corner of the Norfolk Shipbuilding & Drydock, Berkley Plant, Pier No. 1, located at latitude 36°50′08.8″ N, longitude 076°17′37.5″ W; and to the southeast by the Berkley Bridge which crosses the Eastern Branch of the Elizabeth River between Berkley at latitude 36°50′21.5″ N, longitude 076°17′14.5″ W, and Norfolk at latitude 36°50′35″ N, longitude 076°17′10″ W.	1. The 1st consecutive Friday, Saturday, and Sunday in June; or 2. The 2nd consecutive Friday, Saturday, and Sunday in June.	Norfolk Festevents, Ltd.
Pony Penning Swim	The navigable waters of Assateague Channel from shoreline to shoreline, bounded to the east by a line drawn from latitude 37°55′01″ N, longitude 075°22′40″ W, thence south to latitude 37°54′50″ N, longitude 075°22′46″ W; and to the southwest by a line drawn from latitude 37°54′54″ N, longitude 075°23′00″ W, thence east to latitude 37°54′49″ N, longitude 075°22′49″ W.	1. The last Wednesday and following Friday in July; or 2. The 1st Wednesday and following Friday in August.	Chincoteague Volunteer Fire Department.
Poquoson Seafood Festival Workboat Races.	*Regulated area:* The navigable waters of the Back River, Poquoson, VA. The following locations are within the regulated area: *Race area:* The area is bounded on the north by a line drawn along latitude 37°06′30″ N, bounded on the south by a line drawn along latitude 37°06′15″ N, bounded on the east by a line drawn along longitude 076°18′52″ W, and bounded on the west by a line drawn along longitude 076°19′30″ W. *Buffer zone:* The navigable waters of Back River extending 200 yards outwards from east and west boundary lines, and 100 yards outwards from the north and south boundary lines described in this section. *Spectator area:* Is located along the south boundary line of the buffer zone described in this section and continues to the south for 300 yards.	1. The last Sunday in September; or 2. The 1st Sunday of October; or 3. The 2nd Sunday of October.	City of Poquoson.
Something in the Water	*Regulated Area:* All navigable waters of the North Atlantic Ocean immediately adjacent to Virginia Beach, VA bounded on the south side by a line beginning on the shore line at latitude 36°49′49.20″ N, longitude 75°58′04.54″ W, thence easterly to latitude 36°49′49.27″ N, longitude 75°57′58.49″ W, just seaward of the Rudee Inlet break-wall, thence northerly to latitude 36°51′34.83″ N, longitude 75°58′28.82″ W, adjacent to Neptune's Park at 30th street, thence westerly to the shore line at latitude 36°51′34.83″ N, longitude 75°58′35″ W, and thence southerly along the shore line back to the beginning point. *Buffer zone:* The navigable waters of the North Atlantic Ocean extending 200 yards towards the eastern boundary line described in this section. *Spectator Area:* Spectator craft are not permitted within the regulated area during the enforcement period. The regulated area is established to provide adequate separation between event participants on the beach and prohibit unauthorized waterside entry during the event.	The last Friday, Saturday, and Sunday in April.	Redrock Entertainment Services.
Virginia Boat Club (VBC) Sprints Regatta on the James River.	All navigable waters of the James River in the vicinity of Robious Landing Park, Midlothian, VA. The regulated area includes a section of the James River approximately 1300 yards long and bounded in width by each shoreline, bounded to the east by a line that runs parallel along longitude 077°38′04″ W, and bounded to the west by a line that runs parallel along longitude 077°38′54″ W, north of Robious Landing Park.	1. The 2nd Saturday or Sunday in June; or 2. The 3rd Saturday or Sunday in June.	Virginia Boat Club Richmond, VA.

[1] As noted, the enforcement dates and times for each of the listed events in this table are subject to change. In the event of a change, or for enforcement periods listed that do not allow a specific date or dates to be determined, the Captain of the Port will provide notice to the public by publishing a Notice of Enforcement in the **Federal Register**, as well as, issuing a Broadcaster Notice to Mariner.

(4) *Coast Guard Sector North Carolina—COTP Zone.*

TABLE 4 TO PARAGRAPH (i)(4)

Event	Regulated area	Enforcement [1] period(s)	Sponsor
The Crossing	All navigable waters of Lake Gaston, from shoreline to shoreline, directly under the length of Eaton Ferry Bridge (NC State Route 903), commencing at the southern bridge entrance at latitude 36°30′38″ N, longitude 077°57′53″ W, and extending to the northern bridge entrance at latitude 36°31′19″ N, longitude 077°57′33″ W, and bounded to the west by a line drawn parallel and 100 yards from and the western side of Eaton Ferry Bridge near Littleton, NC.	The 2nd Saturday in August.	Organization to Support the Arts, Infrastructure, and Learning on Lake Gaston, AKA O'SAIL.

TABLE 4 TO PARAGRAPH (i)(4)—Continued

Event	Regulated area	Enforcement [1] period(s)	Sponsor
PPD Ironman North Carolina.	All navigable waters of Masonboro Inlet, shoreline to shoreline starting at location latitude 34°11′13″ N, longitude 077°48′53″ W, thence north along Banks Channel to latitude 34°12′14″ N, longitude 077°48′04″ W, thence west to Motts channel, terminating at Sea Path Marina at latitude 34°12′44″ N, longitude 077°48′25″ W, Wrightsville Beach, NC.	1. The 3rd Friday or Saturday in October; or 2. The 4th Friday or Saturday in October; or 3. The last Friday or Saturday in October.	Ironman, Wilmington, NC.
Roanoke River Races	All navigable waters of the Roanoke River in Plymouth, NC, from approximate positions: Latitude 35°52′25″ N, longitude 076°44′33″ W, then northwest to latitude 35°52′29″ N, longitude 076°44′37″ W, then southwest along the shoreline to latitude 35°52′00″ N, longitude 076°45′31″ W, then south to latitude 35°51′56″ N, longitude 076°45′30″ W, then northeast along the shoreline to the point of origin, a length of approximately one mile.	1. The 1st Saturday and Sunday in August; or 2. The 2nd Saturday and Sunday in August; or 3. The 3rd Saturday and Sunday in August; or 4. The 4th Saturday and Sunday in August; And 1. The 2nd Saturday and Sunday in October; or 2. The 3rd Saturday and Sunday in October; or 3. The 4th Saturday and Sunday in October; or 4. The last Saturday and Sunday in October.	Virginia Outlaw Drag Boat Association (VODBA).
Swim the Loop and Motts Channel Sprint.	All navigable waters surrounding Harbor Island, NC including Intracoastal waterway, Lees Cut, Banks Channel and Motts Channel. Enforcement area extends approximately 100 yards from the shoreline of Harbor Island and is bounded by a line connecting the following points; latitude 34°12′55″ N, longitude 077°48′59″ W, thence northeast to latitude 34°13′16″ N, longitude 077°48′39″ W, thence southeast to latitude 34°13′06″ N, longitude 077°48′18″ W, thence east to latitude 34°13′12″ N, longitude 077°47′41″ W, thence southeast to latitude 34°13′06″ N, longitude 077°47′33″ W, thence south to latitude 34°12′31″ N, longitude 077°47′47″ W, thence southwest to latitude 34°12′11″ N, longitude 077°48′01″ W, thence northwest to latitude 34°12′29″ N, longitude 077°48′29″ W, thence north to latitude 34°12′44″ N, longitude 077°48′32″ W, thence northwest to point of origin.	1. The 4th Saturday or Sunday in September; or 2. The last Saturday or Sunday in September.	Without Limits Coaching, Inc.
Wilmington YMCA Triathlon.	All navigable waters of Motts Channel, from shoreline to shoreline and between Wrightsville Channel Day beacon 14 (LLNR 30220), located at latitude 34°12′17.8″ N, longitude 077°48′09.1″ W, thence westward to Wrightsville Channel Day beacon 25 (LLNR 30255), located at latitude 34°12′52.1″ N, longitude 077°48′53.5″ W.	1. The 3rd, 4th, or last Saturday in September; or 2. The last Saturday in October; or 3. The 1st or 2nd Saturday in November.	Wilmington, NC, YMCA.

[1] As noted, the enforcement dates and times for each of the listed events in this table are subject to change. In the event of a change, or for enforcement periods listed that do not allow a specific date or dates to be determined, the Captain of the Port will provide notice to the public by publishing a Notice of Enforcement in the **Federal Register**, as well as, issuing a Broadcaster Notice to Mariner.

Dated: October 26, 2021.

Laura M. Dickey,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2021–24066 Filed 11–5–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2019–0574; FRL–8814–02–R10]

Approval and Promulgation of Air Quality Implementation Plans; Washington; Low Emission Vehicle Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the Washington State Implementation Plan (SIP) pertaining to adoption by reference of a Low Emission Vehicle (LEV) program by the State of Washington. The Clean Air Act (CAA) grants authority to the EPA to adopt Federal standards relating to the control of emissions from new motor vehicles, and generally preempts states from doing so. However, the CAA provides California the ability to adopt and enforce its own new motor vehicle emission standards, as long as the EPA approves California's standards via a preemption waiver. The CAA also allows other states to adopt California's new motor vehicle emission standards for which the EPA has granted such a

waiver providing other relevant criteria are met. Washington adopted California's LEV emission standards in 2005, effective with new vehicles sold in model year 2009. Washington subsequently amended its new motor vehicle emissions program to incorporate California's LEV updates to its program. The purpose of this SIP revision is to implement programs to reduce vehicle emissions that contribute to formation of ground level ozone and fine particulate matter. Washington did not submit provisions related to greenhouse gas emissions from new motor vehicles or zero-emission vehicles requirements for inclusion in the SIP. The EPA is approving and incorporating by reference Washington's LEV SIP revision, as it relates to criteria pollutants, in accordance with the requirements of the CAA.

DATES: This final rule is effective December 8, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2019–0574. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, EPA Region 10, 1200 Sixth Avenue—Suite 155, Seattle, WA 98101, at (206) 553–0256, or *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us,'' or ''our'' is used, it means the EPA.

I. Background

On August 18, 2021, we proposed to approve and incorporate by reference the provisions of Washington Administrative Code, Chapter 173–423 Low Emission Vehicles submitted by the Department of Ecology (86 FR 46169). The reasons for our proposed approval were stated in the proposed rulemaking and will not be re-stated here. The public comment period for our proposed approval ended on September 17, 2021, and we received one comment in support of the proposed approval. Therefore, we are finalizing our action as proposed.

II. Final Action

The EPA is approving, and incorporating by reference into the Washington SIP, the following provisions of Washington Administrative Code (WAC), Chapter 173–423 Low Emission Vehicles submitted by the Department of Ecology:

- WAC 173–423–010, state effective December 29, 2012;
- WAC 173–423–020, state effective December 31, 2005;
- WAC 173–423–025, state effective December 31, 2005;
- WAC 173–423–030, state effective December 31, 2005;
- WAC 173–423–040, except 173–423–040(3), state effective December 29, 2012;
- WAC 173–423–050, except 173–423–050(2)(g), state effective December 29, 2012;
- WAC 173–423–060, state effective December 29, 2012;
- WAC 173–423–070, except the incorporation by reference of California code sections 1961.1 and 1961.3, state effective January 27, 2019;
- WAC 173–423–080, state effective December 29, 2012;
- WAC 173–423–100, state effective December 29, 2012;
- WAC 173–423–110, state effective December 29, 2012;
- WAC 173–423–120, state effective December 29, 2012;
- WAC 173–423–130, state effective December 31, 2005;
- WAC 173–423–140, state effective December 31, 2005; and
- WAC 173–423–150, state effective December 31, 2005.

III. Incorporation by Reference

In this document, the EPA is finalizing regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the regulations described in section II of this preamble. The EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rule of the EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[1]

IV. Statutory and Executive Order Review

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

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

[1] 62 FR 27968 (May 22, 1997).

The SIP is not approved to apply on any Indian reservation land in Washington except as specifically noted below and is also not approved to apply in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Washington's SIP is approved to apply on non-trust land within the exterior boundaries of the Puyallup Indian Reservation, also known as the 1873 Survey Area. Under the *Puyallup Tribe of Indians Settlement Act of 1989,* 25 U.S.C. 1773, Congress explicitly provided state and local agencies in Washington authority over activities on non-trust lands within the 1873 Survey Area. Consistent with EPA policy, the EPA provided a consultation opportunity to the Puyallup Tribe in a letter dated July 15, 2019.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 7, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: October 29, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart WW—Washington

■ 2. In § 52.2470(c), Table 1 is amended by adding the heading Washington Administrative Code, Chapter 173–423—Low Emission Vehicles'' immediately after the entry for ''173–415–070'' titled and adding entries for ''173–423–010'', ''173–423–020'', ''173–423–025'', ''173–423–030'', ''173–423–040'', ''173–423–050'', ''173–423–060'', ''173–423–070'', ''173–423–080'', ''173–423–100'', ''173–423–110'', ''173–423–120'', ''173–423–130'', ''173–423–140'', and ''173–423–150'' under the newly added heading to read as follows:

§ 52.2470 Identification of plan.

* * * * *

(c) * * *

TABLE 1—REGULATIONS APPROVED STATEWIDE

[Not applicable in Indian reservations (excluding non-trust land within the exterior boundaries of the Puyallup Indian Reservation) and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction]

State citation	Title/subject	State effective date	EPA approval date	Explanations
*	*	*	*	*
Washington Administrative Code, Chapter 173–423—Low Emission Vehicles				
173–423–010	Purpose	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–020	Applicability	12/31/05	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–025	Effective Date	12/31/05	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–030	Incorporation by Reference	12/31/05	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–040	Definitions and Abbreviations	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	Except 173–423–040(3).
173–423–050	Requirement to Meet California Vehicle Emission Standards.	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	Except 173–423–050(2)(g).
173–423–060	Exemptions	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–070	Emission Standards, Warranty, Recall and Other California Provisions Adopted by Reference.	1/27/19	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	Except the incorporation by reference of California code sections 1961.1 and 1961.3.
173–423–080	Fleet Average Nonmethane Organic Gas (NMOG) and NMOG Plus NO_X Exhaust Emission Requirements, Reporting and Compliance..	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–100	Manufacturer Delivery Reporting Requirements.	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–110	Warranty Requirements	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	

TABLE 1—REGULATIONS APPROVED STATEWIDE—Continued

[Not applicable in Indian reservations (excluding non-trust land within the exterior boundaries of the Puyallup Indian Reservation) and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction]

State citation	Title/subject	State effective date	EPA approval date	Explanations
173–423–120	Recalls	12/29/12	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–130	Surveillance	12/31/05	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–140	Enforcement	12/31/05	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	
173–423–150	Severability	12/31/05	11/8/21, [INSERT **FEDERAL REGISTER** CITATION].	

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[FR Doc. 2021–24158 Filed 11–5–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 713

[EPA–HQ–OPPT–2017–0421; FRL–8523–02–OCSPP]

RIN 2070–AK93

Response to Vacatur of Certain Provisions of the Mercury Inventory Reporting Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is revising regulations associated with persons who must report data to the Agency's mercury inventory established under the Toxic Substances Control Act (TSCA). Those reporting requirements were set forth in a final rule entitled ''Reporting Requirements for TSCA Mercury Inventory: Mercury'' (hereafter ''mercury inventory reporting rule''). These revisions implement an order issued by the United States Court of Appeals for the Second Circuit (Second Circuit), on June 5, 2020.

DATES: This final rule is effective on December 8, 2021.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0421, is available at *https://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Thomas Groeneveld, Existing Chemicals Resource Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1188; email address: *groeneveld.thomas@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you import mercury-added products. 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 the following:

- Gold ore mining (NAICS code 212221).
- Lead ore and zinc ore mining (NAICS code 212231).
- All other metal ore mining (NAICS code 212299).
- Asphalt shingle and coating materials manufacturing (NAICS code 324122).
- Synthetic dye and pigment manufacturing (NAICS code 325130).
- Other basic inorganic chemical manufacturing (NAICS code 325180).
- All other basic organic chemical manufacturing (NAICS code 325199).
- Plastics material and resin manufacturing (NAICS code 325211).
- Pesticide and other agricultural chemical manufacturing (NAICS code 325320).
- Medicinal and botanical manufacturing (NAICS code 325411).
- Pharmaceutical preparation manufacturing (NAICS code 325412).
- Biological product (except diagnostic) manufacturing (NAICS code 325414).
- Paint and coating manufacturing (NAICS code 325510).
- Adhesive manufacturing (NAICS code 325520).
- Custom compounding of purchased resins (NAICS code 325991).
- Photographic film, paper, plate, and chemical manufacturing (NAICS code 325992).
- All other miscellaneous chemical product and preparation manufacturing (NAICS code 325998).
- Unlaminated plastics film and sheet (except packaging) manufacturing (NAICS code 326113).
- Unlaminated plastics profile shape manufacturing (NAICS code 326121).
- Urethane and other foam product (except polystyrene) manufacturing (NAICS code 326150).
- All other plastics product manufacturing (NAICS code 326199).
- Tire manufacturing (NAICS code 326211).
- All other rubber product manufacturing (NAICS code 326299).
- Iron and steel mills and ferroalloy manufacturing (NAICS code 331110).
- Rolled steel shape manufacturing (NAICS code 331221).

- Alumina refining and primary aluminum production (NAICS code 331313).
- Secondary smelting and alloying of aluminum (NAICS code 331314).
- Nonferrous metal (except aluminum) smelting and refining (NAICS code 331410).
- Secondary smelting, refining, and alloying of nonferrous metal (except copper and aluminum) (NAICS code 331492).
- Iron foundries (NAICS code 331511).
- Steel foundries (except investment) (NAICS code 331513).
- Fabricated structural metal manufacturing (NAICS code 332312).
- Industrial valve manufacturing (NAICS code 332911).
- Ammunition except small arms manufacturing (NAICS code 332993).
- Small arms, ordnance, and ordnance accessories manufacturing (NAICS code 332994).
- All other miscellaneous fabricated metal product manufacturing (NAICS code 332999).
- Food product machinery manufacturing (NAICS code 333294).
- Office machinery manufacturing (NAICS code 333313).
- Other commercial and service industry machinery manufacturing (NAICS code 333319).
- Heating equipment (except warm air furnaces) manufacturing (NAICS code 333414).
- Air-conditioning and warm air heating equipment and commercial and industrial refrigeration equipment manufacturing (NAICS code 333415).
- Pump and pumping equipment manufacturing (NAICS code 333911).
- Bare printed circuit board manufacturing (NAICS code 334412).
- Semiconductor and related device manufacturing (NAICS code 334413).
- Other electronic component manufacturing (NAICS code 334419).
- Electromedical and electrotherapeutic apparatus manufacturing (NAICS code 334510). Search, detection, navigation, guidance, aeronautical, and nautical system and instrument manufacturing (NAICS code 334511).
- Automatic environmental control manufacturing for residential, commercial, and appliance use (NAICS code 334512).
- Instruments and related products manufacturing for measuring, displaying, and controlling industrial process variables (NAICS code 334513).
- Totalizing fluid meter and counting device manufacturing (NAICS code 334514).
- Instrument manufacturing for measuring and testing electricity and electrical signals (NAICS code 334515).
- Analytical laboratory instrument manufacturing (NAICS code 334516).
- Watch, clock, and part manufacturing (NAICS code 334518).
- Other measuring and controlling device manufacturing (NAICS code 334519).
- Electric lamp bulb and part manufacturing (NAICS code 335110).
- Commercial, industrial, and institutional electric lighting fixture manufacturing (NAICS code 335122).
- Other lighting equipment manufacturing (NAICS code 335129).
- Electric house wares and household fan manufacturing (NAICS code 335211).
- Household vacuum cleaner manufacturing (NAICS code 335212).
- Household cooking appliance manufacturing (NAICS code 335221).
- Household refrigerator and home freezer manufacturing (NAICS code 335222).
- Household laundry equipment manufacturing (NAICS code 335224).
- Other major household appliance manufacturing (NAICS code 335228).
- Switchgear and switchboard apparatus manufacturing (NAICS code 335313).
- Relay and industrial control manufacturing (NAICS code 335314).
- Primary battery manufacturing (NAICS code 335912).
- Current-carrying wiring device manufacturing (NAICS code 335931).
- All other miscellaneous electrical equipment and component manufacturing (NAICS code 335999).
- Automobile manufacturing (NAICS code 336111).
- Light truck and utility vehicle manufacturing (NAICS code 336112).
- Heavy duty truck manufacturing (NAICS code 336120).
- Motor home manufacturing (NAICS code 336213).
- Travel trailer and camper manufacturing (NAICS code 336214).
- Other aircraft parts and auxiliary equipment manufacturing (NAICS code 336413).
- Boat building (NAICS code 336612).
- Motorcycles and parts manufacturing (NAICS code 336991).
- Surgical and medical instrument manufacturing (NAICS code 339112).
- Costume jewelry and novelty manufacturing (NAICS code 339914).
- Game, toy, and children's vehicle manufacturing (NAICS code 339932).
- Sign manufacturing (NAICS code 339950).
- Other chemical and allied products merchant wholesalers (NAICS code 424690).
- Research and development in the physical, engineering, and life sciences (except biotechnology) (NAICS code 541712).
- Hazardous waste treatment and disposal (NAICS code 562211).
- Other nonhazardous waste treatment and disposal (NAICS code 562219).
- Materials recovery facilities (NAICS code 562920).
- National security (NAICS code 928110).

B. What action is the Agency taking?

In June 2018, EPA finalized a rule to require reporting from persons who manufacture (including import) mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process (Ref. 1). That rule was challenged in the Second Circuit by the Natural Resources Defense Council and several state attorneys general in July 2018. Oral arguments were held on November 20, 2019, and the court issued its decision on June 5, 2020. The petitioners argued that three exemptions to the reporting requirements violated the statutory mandate within TSCA section 8(b)(10). The Agency argued that the three exemptions were lawful because EPA determined certain reporting to be duplicative or burdensome per existing EPA or other mercury-related reporting requirements. Duplicative or overly burdensome reporting requirements are prohibited under TSCA section 8(a)(5). The Agency prevailed on two issues, but the Second Circuit vacated the exemption at 40 CFR 713.7(b)(2) for persons who import pre-assembled products that contain a mercury-added component (Ref. 2). As a result, such persons are now required to report pursuant to 40 CFR 713.7(b). This rule is effectuating the vacatur ordered by the Second Circuit by making necessary amendments to the corresponding text in 40 CFR 713.7(b).

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

EPA is issuing this final rule pursuant to TSCA section 8(b)(10)(D) (15 U.S.C. 2607(b)(10)(D)), which authorizes EPA to require reporting in order to assist in preparing the inventory of mercury supply, use and trade in the United States. In addition, section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public 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 revising these provisions without prior proposal and opportunity for comment, because these revisions simply undertake the ministerial task of implementing the court order vacating an exemption at 40 CFR 713.7(b)(2) and making the necessary amendments to corresponding text in 40 CFR 713.7(b). As a matter of law, the order issued by the Second Circuit on June 5, 2020 vacated the reporting exemption for persons who manufacture (including import) a mercury-added product where that person is ''engaged only in the import of a product that contains a component that is a mercury-added product.'' It is, therefore, unnecessary to provide notice and an opportunity for comment on this action, which merely carries out the court's order.

D. Which regulations is EPA removing and replacing?

EPA is effectuating the Second Circuit vacatur of the exemption for persons who manufacture (including import) a mercury-added product where that person is ''engaged only in the import of a product that contains a component that is a mercury-added product.'' Therefore, the current text at 40 CFR 713.7(b)(2) will be removed and replaced (with appropriate textual and numbering updates) with the text currently found at 40 CFR 713.7(b)(3).

E. What are the estimated burdens associated with the removed and replaced regulations?

EPA has prepared an economic analysis of the potential impacts associated with this rulemaking (Ref. 3). This economic analysis estimates and evaluates the total costs and benefits for additional reporters to the mercury inventory reporting rule due to this rulemaking (*i.e.,* those that import products that contain a component that is a mercury-added product). EPA is considering an estimate of 756 as the number of sites potentially subject to the amended rule, which, under the revised requirements, is now applicable to imports of products that contain a component that is a mercury-added product. EPA estimates that as many as 657 sites will submit reports due to the revised requirements. This is the incremental difference between the number of actual reporters to the mercury inventory reporting rule during the 2019 submission period, and the expected number of total reporters based on the number of entities that report to the Interstate Mercury Education & Reduction Clearinghouse (IMERC) or to EPA's Chemical Data Reporting (CDR) or Toxics Release Inventory (TRI). More details on the methodology used can be found in the Agency's economic analysis (Ref. 3).

The chief benefit of the final rule is the collection of detailed data on mercury, which will serve as a basis to recommend actions to further reduce mercury use in the United States, as required at TSCA section 8(b)(10)(C). Another benefit is the use of information collected under the final rule to help the United States implement its obligations under the Minamata Convention, a multilateral environmental agreement that addresses specific human activities that are contributing to widespread mercury pollution. While there are no quantified benefits for the final rule, the statutory mandates at TSCA sections 8(b)(10)(C) and (D) (15 U.S.C. 2607(b)(10)(C) and (D)), specifically call for and authorizes a rule to support an inventory of mercury supply, use, and trade in the United States, to identify any manufacturing processes or products that intentionally add mercury, and to recommend actions to achieve further reductions in mercury use. As described in the Agency's economic analysis, unquantified benefits include providing increased information on mercury and assisting in the reduction of mercury use (Ref. 3). To the extent that the information gathered through this rule is used to reduce mercury use, benefits to society will result from a reduction in exposure.

- *Benefits:* The final rule will provide information on mercury and mercury-added products to which the Agency (and the public) does not currently have access. To the extent that the information gathered through this final rule is used to reduce mercury use, benefits to society will result from a reduction in risk.
- *Costs:* Total reporter (industry) costs the first year were estimated in 2020$ at $5.1 million, and $3.6 million in subsequent reporting years. Annualized over 10 years, the reporter costs are $1.5 million at both 3% and 7% discount rates. Agency costs are $729 per report per year, for an annualized cost of $177,000 and $181,000 at 3% and 7% discount rates, respectively. Therefore, the total annualized costs are expected to be approximately $1.7 million at both 3% and 7% discount rates. The total burden of the rule is expected to be approximately 212,000 hours over the 10-year analysis period. These estimates include compliance determination, rule familiarization, CBI substantiation, electronic reporting, and recordkeeping, in addition to completing reporting requirements.
- *Small Entity Impacts:* The final rule will impact 203 companies that meet the U.S. Small Business Administration (SBA) definitions for their respective NAICS classifications. Among the total 657 sites regulated under the rule, EPA found that the costs of the rule exceed 3 percent of the value of sales for 2 small businesses, and an additional 3 small businesses may incur costs at between 1 and 3 percent of the value of sales. EPA is unable to determine whether these 5 small businesses actually import products that contain a component that is a mercury-added product.
- *Environmental Justice and Protection of Children:* The Agency believes that the information collected under this rule, if finalized, will assist EPA and others in determining the potential hazards and risks associated with elemental mercury and mercury compounds. Although not directly impacting environmental justice-related concerns, this information will enable the Agency to better protect human health and the environment, including in low-income and minority communities. The rule is directed at all mercury-added products that are manufactured or imported into the United States. All consumers of these chemicals and the products made from them and all workers who come into contact with these chemicals could benefit if data regarding the chemicals' health and environmental effects were developed. Therefore, it does not appear that the costs and the benefits of the rule will be disproportionately distributed across different geographic regions or among different categories of individuals.
- *Effects on State, Local, and Tribal Governments:* Government entities are not expected to be subject to the rule's requirements, which apply to entities that manufacture (including import) mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process. The final rule does not have a significant intergovernmental mandate, significant or unique effect on small governments, or have Federalism implications.

II. 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 physically located in the docket. For assistance in locating these other documents, please consult

the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. ''Reporting Requirements for TSCA Mercury Inventory: Mercury;'' Final Rule. **Federal Register** (83 FR 30054, June 27, 2018) (FRL–9979–74).
2. United States Court of Appeals for the Second Circuit. *Natural Resources Defense Council, Inc. and State of Vermont* v. *United States Environmental Protection Agency,* 961 F.3d 160 (2d. Cir. 2020).
3. EPA. ''Economic Analysis for the Final Rule on Revisions to the Reporting Requirements for the TSCA Mercury Inventory.''

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

The revised information collection activities in this rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.,* as part of a request to renew the existing approval under OMB Control No. 2070–0207. The renewal Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2567.04. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The revised information collection requirements are not enforceable until OMB approves them.

The ICR renewal request explains the necessary adjustments related to the Second Circuit vacatur. Applying the reporting requirements identified in the 2018 final rule to persons who manufacture (including import) a mercury-added product will provide EPA with more complete information necessary to prepare and periodically update an inventory of mercury supply, use, and trade in the United States, as required by TSCA section 8(b)(10)(D). These reporting requirements will help the Agency to prepare subsequent, triennial publications of the inventory, as well as to carry out the requirement of TSCA section 8(b)(10)(C) to identify any manufacturing processes or products that intentionally add mercury and recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use. EPA intends to use information collected under the rule to assist in efforts to reduce the use of mercury in products and processes and to facilitate reporting on implementation of the Minamata Convention by the United States. Respondents may claim some of the information reported to EPA under the final rule as CBI under TSCA section 14. TSCA section 14(c) requires a supporting statement and certification for confidentiality claims asserted after June 22, 2016.

Respondents/affected entities: Manufacturers, importers, and processors of mercury and mercury-added products.

Respondent's obligation to respond: Mandatory (15 U.S.C. 2607(b)(10)(D)).

Estimated number of respondents: 756.

Frequency of response: Triennially.

Total estimated annual burden: 17,348 hours (averaged over 3 years). Burden is defined at 5 CFR 1320.3(b).

Total estimated annual cost: $1,384,999 (averaged over 3 years), includes $0 annualized capital or operation and maintenance costs.

Change in burden estimates: Based on the numbers of reporters of mercury data to the IMERC Mercury-added Products Database, as well as EPA's TRI program and CDR rule, there will be a change in manufacturers (including importers) or processors that could respond to this information collection. The annual public burden for this collection of information is estimated about 23 hours per respondent. This request represents a decrease of 9 hours per respondent from that currently in the OMB inventory, or a total decrease of 20,522 hours (from 72,567 to 52,045 hours). This change reflects a decrease in rule familiarization burden, a decrease in form completion burden due to mercury export prohibitions, and changes in the number of estimated respondents.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves the renewal ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

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. This rule is not subject to notice and comment requirements because the Agency has invoked the APA ''good cause'' exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531 through 1538, and does not significantly or uniquely affect small governments. As such, the requirements of sections 202, 203, 204, or 205 of UMRA do not apply to this action.

E. Executive Order 13132: Federalism

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

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). It will not have any effect 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, as specified in the Order. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks 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. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This final rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not expected to affect energy supply, distribution, or use and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards. Therefore, section 12(d) of NTTAA, 15 U.S.C. 272 *note,* does not apply to this action.

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

This action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This action establishes an information requirement and does not affect the level of protection provided to human health or the environment.

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 713

Environmental protection, Exports, Imports, Manufacturing, Mercury, Trade practices.

Michael S. Regan,
Administrator.

Therefore, for the reasons set forth in the preamble, 40 CFR Chapter I is amended as follows:

PART 713—REPORTING REQUIREMENTS FOR THE TSCA INVENTORY OF MERCURY SUPPLY, USE, AND TRADE

■ 1. The authority citation for part 713 continues to read as follows:

Authority: 15 U.S.C. 2607(b)(10)(D).

■ 2. In § 713.7, paragraph (b) is revised to read as follows:

§ 713.7 Persons who must report.

* * * * *

(b) Any person who manufactures (including imports) a mercury-added product, except:

(1) A person who does not manufacture (including import) a mercury-added product with the purpose of obtaining an immediate or eventual commercial advantage; or

(2) A person engaged only in the manufacture (other than import) of a product that contains a component that is a mercury-added product who did not first manufacture (including import) the component that is a mercury-added product; and

* * * * *

[FR Doc. 2021–24209 Filed 11–5–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 211029–0220]

RIN 0648–BK98

Temporary Rule Authorizing Limited Tow Times in Lieu of Turtle Excluder Devices by Shrimp Trawlers in Specific Louisiana Waters

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule.

SUMMARY: NMFS issues this temporary rule for a period of 30 days, to allow shrimp fishers to use limited tow times as an alternative to Turtle Excluder Devices (TEDs) in specific Louisiana state waters (from 91° 23′ West longitude eastward to the Louisiana/Mississippi border, and seaward out 3 nautical miles (5.6 kilometers)). This action is necessary because environmental conditions resulting from Hurricane Ida are preventing fishers from using TEDs effectively.

DATES: Effective from November 5, 2021 through December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Michael Barnette, 727–551–5794.

SUPPLEMENTARY INFORMATION:

Background

All sea turtles that occur in U.S. waters are listed as either endangered or threatened under the Endangered Species Act of 1973 (ESA). The Kemp's ridley (*Lepidochelys kempii*), leatherback (*Dermochelys coriacea*), and hawksbill (*Eretmochelys imbricata*) turtles are listed as endangered. The loggerhead (*Caretta caretta*) and green (*Chelonia mydas*) turtles are listed as threatened, except for breeding populations of green turtles in Florida and on the Pacific coast of Mexico, which are listed as endangered.

Sea turtles are incidentally taken, and some are killed, as a result of numerous activities, including fishery-related trawling activities in the Gulf of Mexico and along the Atlantic seaboard. Under the ESA and its implementing regulations, the taking of sea turtles is prohibited, with exceptions identified in 50 CFR 223.206(d), or according to the terms and conditions of a biological opinion issued under section 7 of the ESA, or according to an incidental take permit issued under section 10 of the ESA. The incidental taking of turtles during shrimp or summer flounder trawling is exempted from the taking prohibition of section 9 of the ESA, if the conservation measures specified in the sea turtle conservation regulations (50 CFR part 223) are followed. The regulations require most shrimp trawlers and summer flounder trawlers operating in the southeastern United States (Atlantic area, Gulf area, and summer flounder sea turtle protection area, see 50 CFR 223.206) to have a NMFS-approved TED installed in each net that is rigged for fishing to allow sea turtles to escape. TEDs currently approved by NMFS include single-grid hard TEDs and hooped hard TEDs conforming to a generic description, the flounder TED, and one type of soft TED—the Parker soft TED (see 50 CFR 223.207).

TEDs incorporate an escape opening, usually covered by a webbing flap, which allows sea turtles to escape from trawl nets. To be approved by NMFS, a TED design must be shown to be 97 percent effective in excluding sea turtles during testing based upon specific testing protocols (50 CFR 223.207(e)(1)). Approved hard TEDs are described in the regulations (50 CFR 223.207(a)) according to generic criteria based upon certain parameters of TED design, configuration, and installation, including height and width dimensions of the TED opening through which the turtles escape.

The regulations governing sea turtle take prohibitions and exemptions provide for the use of limited tow times as an alternative to the use of TEDs for vessels with certain specified characteristics or under certain special circumstances. The provisions of 50 CFR 223.206(d)(3)(ii) specify that the NOAA Assistant Administrator for Fisheries (AA) may authorize compliance with tow time restrictions as an alternative to the TED requirement if the AA determines that the presence of algae, seaweed, debris, or other

special environmental conditions in a particular area makes trawling with TED-equipped nets impracticable. Namely, TEDs can become clogged with debris, which can prevent target species from passing into the codend of the net and sea turtles from escaping through the TED opening. The provisions of 50 CFR 223.206(d)(3)(i) specify the maximum tow times that may be used when tow time limits are authorized as an alternative to the use of TEDs. Each tow may be no more than 55 minutes from April 1 through October 31 and no more than 75 minutes from November 1 through March 31, as measured from the time that the trawl doors enter the water until they are removed from the water. For a trawl that is not attached to a door, the tow time begins at the time the codend enters the water and ends at the time the codend is emptied of catch on deck. These tow time limits are designed to minimize the level of mortality of sea turtles that are captured by trawl nets not equipped with TEDs.

Recent Events

On September 21, 2021, the NMFS Southeast Regional Administrator received a request from the Louisiana Department of Wildlife and Fisheries (LDWF) to allow the use of tow times as an alternative to TEDs because of excessive storm-related debris on the fishing grounds as a result of Hurricane Ida. The request identified the affected area as inside and outside waters from the Mississippi/Louisiana state line westward to the Freshwater Bayou Canal, located due west of Vermilion Bay. When a TED is clogged with debris it can no longer catch shrimp effectively, nor can it effectively exclude turtles. Despite contrary assertions in the request from LDWF, sea turtle interactions with shrimp trawls have been extensively documented in Louisiana state waters by NMFS observers, and a temporary exemption from the TED requirements can help minimize the effects of those interactions on sea turtles during such special conditions. Louisiana has stated that their marine enforcement agents will enforce the tow time restrictions.

Field investigation by the Southeast Fisheries Science Center, Pascagoula Lab, Gear Monitoring Team determined debris is affecting fisher's ability to use TEDs effectively within the area bounded by 91° 23′ West longitude (*i.e.,* where the COLREGS demarcation line intersects the ship channel coming out of the Atchafalaya River), eastward to the Louisiana/Mississippi border, and seaward out 3 nautical miles (5.6 kilometers).

Special Environmental Conditions

The AA finds that debris washed into hurricane-affected Louisiana state waters has created special environmental conditions that make trawling with TED-equipped nets impracticable. Therefore, the AA issues this notification to authorize the use of restricted tow times as an alternative to the use of TEDs in specific Louisiana state waters (from 91° 23′ West longitude eastward to the Louisiana/Mississippi border, and seaward out 3 nautical miles (5.6 kilometers)). Tow times must be limited to no more than 55 minutes until October 31, and no more than 75 minutes thereafter, as measured from the time that the trawl doors enter the water until they are removed from the water. For a trawl that is not attached to a door, the tow time begins at the time the codend enters the water and ends at the time the codend is emptied of catch on deck.

Continued Use of TEDs

NMFS encourages shrimp trawlers in the affected areas to continue to use TEDs if they can do so effectively, even though they are authorized under this action to use restricted tow times.

NMFS gear experts have provided several general operational recommendations to fishers to maximize the debris exclusion ability of TEDs that may allow some fishers to continue using TEDs without resorting to restricted tow times. To exclude debris, NMFS recommends the use of hard TEDs made of either solid rod or of hollow pipe that incorporate a bent angle at the escape opening, in a bottom-opening configuration. In addition, the installation angle of a hard TED in the trawl extension is an important performance element in excluding debris from the trawl. High installation angles can trap debris either on or in front of the bars of the TED; NMFS recommends an installation angle of 45°, relative to the normal horizontal flow of water through the trawl, to optimize the TED's ability to exclude turtles and debris. Furthermore, the use of accelerator funnels, which are allowable modifications to hard TEDs, is not recommended in areas with heavy amounts of debris or vegetation. Lastly, the webbing flap that is usually installed to cover the turtle escape opening may be modified to help exclude debris quickly: The webbing flap can either be cut horizontally to shorten it so that it does not overlap the frame of the TED or be slit in a fore-and-aft direction to facilitate the exclusion of debris. The use of the double cover flap TED will also aid in debris exclusion.

All of these recommendations represent legal configurations of TEDs for shrimpers fishing in the affected areas. This action does not authorize any other departure from the TED requirements, including any illegal modifications to TEDs. In particular, if TEDs are installed in trawl nets, they may not be sewn shut.

Alternative to Required Use of TEDs

The authorization provided by this rule applies to all shrimp trawlers that would otherwise be required to use TEDs in accordance with the requirements of 50 CFR 223.206(d)(2) who are operating in hurricane-affected Louisiana state waters (*i.e.,* from 91° 23′ West longitude eastward to the Louisiana/Mississippi border, and seaward out 3 nautical miles (5.6 kilometers)) for a period of 30 days. Through this temporary rule, shrimp trawlers may choose either restricted tow times or TEDs to comply with the sea turtle conservation regulations, as prescribed above.

Alternative to Required Use of TEDs; Termination

The AA, at any time, may withdraw or modify this temporary authorization to use tow time restrictions in lieu of TEDs through publication of a document in the **Federal Register**, if necessary to ensure adequate protection of endangered and threatened sea turtles. Under this procedure, the AA may modify the affected area or impose any necessary additional or more stringent measures, including more restrictive tow times, synchronized tow times, or withdrawal of the authorization if the AA determines that the alternative authorized by this rule is not sufficiently protecting turtles or no longer needed. The AA may also terminate this authorization if information from enforcement, state authorities, or NMFS indicates compliance cannot be monitored effectively. This authorization will expire automatically on December 6, 2021, unless it is explicitly extended through another notification published in the **Federal Register**.

Classification

This action has been determined to be not significant for purposes of Executive Order 12866.

The AA has determined that this action is necessary to respond to an environmental situation to allow more efficient fishing for shrimp, while providing effective protection for endangered and threatened sea turtles pursuant to the ESA and applicable regulations.

Pursuant to 5 U.S.C. 553(b)(B), the AA finds that there is good cause to waive prior notice and opportunity to comment on this rule. The AA finds that unusually high amounts of debris are creating special environmental conditions that make trawling with TED-equipped nets impracticable. Prior notice and opportunity to comment are impracticable and contrary to the public interest in this instance because providing notice and comment would prevent the agency from providing the affected industry relief from the effects of Hurricane Ida in a timely manner, while continuing to provide effective protection for sea turtles.

For the same reasons, the AA finds that there is good cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(d)(3).

Since prior notice and an opportunity for public comment are not required to be provided for this action by 5 U.S.C. 553, or by any other law, the analytical requirements of 5 U.S.C. 601 *et seq.* are inapplicable.

Authority: 16 U.S.C. 1531–1543.

Dated: November 1, 2021.

Carrie Diane Robinson,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–24175 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 211103–0223; RTID 0648–XX074]

Atlantic Surfclam and Ocean Quahog Fisheries; 2022 Fishing Quotas for Atlantic Surfclams and Ocean Quahogs; and Suspension of Atlantic Surfclam Minimum Size Limit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces that the quotas for the Atlantic surfclam and ocean quahog fisheries for 2022 will remain status quo. NMFS also suspends the minimum size limit for Atlantic surfclams for the 2022 fishing year. Regulations for these fisheries require NMFS to notify the public of the allowable harvest levels for Atlantic surfclams and ocean quahogs from the Exclusive Economic Zone even if the previous year's quota specifications remain unchanged.

DATES: Effective January 1, 2022, through December 31, 2022.

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, 978–281–9341.

SUPPLEMENTARY INFORMATION: The Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP) requires that NMFS issue a notice in the **Federal Register** of the upcoming year's quota, even if the quota remains unchanged from the previous year. At its June 2021 meeting, the Mid-Atlantic Fishery Management Council recommended no change to the quota specifications for Atlantic surfclams and ocean quahogs for the 2022 fishing year. We are announcing 2022 quota levels of 3.4 million bushels (bu) (181 million L) for Atlantic surfclams, 5.36 million bu (288 million L) for ocean quahogs, and 100,000 Maine bu (3.52 million L) for Maine ocean quahogs. These quotas were published as projected 2022 limits in the **Federal Register** on May 13, 2021 (86 FR 26186). This rule establishes these quotas as unchanged from 2021 and final.

The regulations at 50 CFR 648.75(b)(3) allow the Regional Administrator to annually suspend the minimum size limit for Atlantic surfclams unless discard, catch, and biological sampling data indicate that 30 percent or more of the Atlantic surfclam resource have a shell length less than 4.75 inches (in) (121 millimeters (mm)) and the overall reduced size is not attributable to harvest from beds where growth of the individual clams has been reduced because of density-dependent factors. At its June 2021 meeting, the Council recommended the Regional Administrator suspend the minimum size limit for Atlantic surfclams for the 2022 fishing year. Commercial surfclam data for 2021 indicated that 16.9 percent of the overall commercial landings were composed of surfclams that were less than the 4.75-in (121-mm) default minimum size.

Based on the information available, the Regional Administrator concurs with the Council's recommendation and is suspending the minimum size limit for Atlantic surfclams for the upcoming fishing year (January 1 through December 31, 2022).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator for Fisheries, NOAA, has determined that this rule is consistent with the Atlantic Surfclam and Ocean Quahog FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This action does not introduce any new reporting, recordkeeping, or other compliance requirements. This rule does not duplicate, overlap, or conflict with other Federal rules.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be unnecessary and contrary to the public interest. The public was given the opportunity to comment on the proposed rule for the 2021–2026 specifications (86 FR 9901, February 17, 2021), including the projected 2022 specifications, which remain unchanged. Delaying this action would prolong public uncertainty about the final quotas for the 2022 fishing year. The public and industry participants expect this action because we previously alerted the public that we would conduct this review in interim years of the multi-year specifications and announce the final quotas before or as close as possible to the January 1 start of the fishing year. This rule could not be published earlier because of the time necessary to collect data and conduct the analysis to support suspending the minimum size limit for Atlantic surfclams.

This rule is exempt from the requirements of Executive Order 12866.

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are inapplicable.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 3, 2021.

Carrie Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–24390 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[Docket No. 211101–0222]

RIN 0648–BK63

Fisheries of the Atlantic; Atlantic Migratory Group Cobia; Amendment 1 and Addendum 1 to Amendment 1

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues regulations related to Amendment 1, and Addendum 1 to Amendment 1, to the Interstate Fishery Management Plan (FMP) for Atlantic Migratory Group Cobia (Interstate FMP), as prepared and submitted by the Atlantic States Marine Fisheries Commission (ASMFC). As described in Amendment 1 and Addendum 1, this final rule revises the commercial quota and the process for a commercial quota closure for Atlantic migratory group cobia (Atlantic cobia) in Federal waters. The purpose of this final rule is to increase the commercial quota as a result of the most recent stock assessment and to allow the ASMFC to monitor commercial landings for any needed commercial in-season closure while ensuring the long-term sustainability of the Atlantic cobia stock.

DATES: This final rule is effective November 8, 2021.

ADDRESSES: Electronic copies of Amendment 1 and Addendum 1 may be obtained from the ASMFC website at *http://www.asmfc.org/uploads/file/6009e765AtlanticCobia_AddendumI_Oct2020.pdf.*

FOR FURTHER INFORMATION CONTACT: Frank Helies, telephone: 727–824–5305, or email: *Frank.Helies@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for Atlantic cobia in Federal waters is managed under the authority of the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic Coastal Act) by regulations at 50 CFR part 697. Separate migratory groups of cobia are managed in the Gulf of Mexico and Atlantic. Atlantic cobia is managed from Georgia through New York. The southern management boundary for Atlantic cobia is a line that extends due east of the Florida and Georgia state border at 30°42′45.6″ N latitude. The northern management boundary for Atlantic cobia is the jurisdictional boundary between the Mid-Atlantic and New England Fishery Management Councils, as specified in 50 CFR 600.105(a).

The final rule to implement Amendment 31 to the FMP for Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region and Amendment 1 to the Interstate FMP removed Atlantic cobia from Federal management under the Magnuson-Stevens Fishery Conservation and Management Act and transitioned the management of Atlantic cobia in Federal waters to the ASMFC under the Atlantic Coastal Act (84 FR 4733, February 19, 2019). All weights described in this rule are in round and eviscerated weight, combined.

On September 2, 2021, NMFS published a proposed rule for Amendment 1 and Addendum 1 and requested public comment (86 FR 49284). The proposed rule and Amendment 1 and Addendum 1 outline the rationale for the actions contained in this final rule. A summary of the management measures described in Amendment 1 and Addendum 1 and implemented by this final rule is described below.

Background

The ASMFC approved Amendment 1 to the Interstate FMP in 2019 and Addendum 1 to Amendment 1 in 2020. Amendment 1 and Addendum 1 provide for an increase in the commercial quota and a revision to the process for a commercial in-season closure. This final rule serves to implement certain measures in Federal waters contained within Amendment 1 and Addendum 1.

In 2020, a new Southeast Data, Assessment, and Review (SEDAR) assessment was completed for Atlantic cobia (SEDAR 58). SEDAR 58 indicated that Atlantic cobia was not overfished or undergoing overfishing, and that the allowable harvest could be increased based on updated commercial and recreational catch estimates. Based on the results of the SEDAR 58 and new stock projections from February 2020, in October of 2020, the ASFMC approved an increase to the Atlantic cobia annual total harvest quota of 80,112 fish for the 2020–2022 fishing seasons. Through Amendment 1 and Addendum 1, the ASMFC also adjusted the commercial and recreational allocation percentages and changed the methodology used to close the commercial sector when the quota is reached.

The ASMFC revised the total Atlantic cobia quota sector allocations from 8 percent to 4 percent for the commercial harvest and from 92 percent to 96 percent for the recreational harvest, to account for changes in the recreational catch estimates from the Marine Recreational Information Program Fishing Effort Survey. When defining these allocations in terms of numbers of fish, the updated allocations would result in a commercial quota of 3,204 fish and a recreational quota of 76,908 fish. As described in Amendment 1 and Addendum 1, using an average commercial weight of 22.82 lb (10.35 kg), this is equivalent to a commercial quota of 73,116 lb (33,165 kg) in round and gutted weight, combined. In addition, the ASMFC would closely monitor commercial landings to ensure the commercial quota is not exceeded.

Management Measures Contained in This Final Rule

This final rule modifies the commercial quota and the process for closing the commercial sector in Federal waters when the quota is reached.

Commercial Quota

The current Atlantic cobia commercial quota of 50,000 lb (22,680 kg) was established through the final rule to implement Amendment 1 to the Interstate FMP (84 FR 4733, February 19, 2019). As a result of SEDAR 58, this final rule increases the commercial quota to 73,116 lb (33,165 kg). The ASMFC is responsible for monitoring of commercial landings during the fishing year.

Process To Close the Commercial Sector

The current process requires an in-season closure in Federal waters during the fishing year for the commercial sector when the quota is reached or projected to be reached. When the NMFS Science and Research Director estimates that the sum of commercial landings (cobia that are sold) reaches or is projected to reach the commercial quota, then NMFS will prohibit the sale and purchase of cobia for the remainder of that fishing year (a commercial closure). For example, in 2020, NMFS projected that commercial landings would reach the commercial quota on November 6, and therefore, NMFS closed the commercial sector on November 6, 2020, through December 31, 2020 (85 FR 70085; November 4, 2020).

This final rule retains the possibility of an in-season closure if commercial landings reach the quota. This final rule also changes the closure language in the current regulations regarding in-season quota monitoring so that commercial landings will be monitored by the ASMFC and not by NMFS. Currently, NMFS monitors the commercial quota and closes the commercial sector when the quota is met or projected to be met. The new process transfers quota monitoring responsibility to the ASMFC. Because Atlantic cobia are primarily landed in state waters, the ASFMC determined that they are better suited to monitor cobia landings and ensure the risk of early closures is minimized. During the fishing year, if the ASMFC estimates that the sum of commercial landings (cobia that are sold), reaches or is projected to reach the commercial quota, then the ASMFC would notify NMFS of the need for a

commercial closure of the exclusive economic zone (EEZ) and NMFS would close the commercial sector. During any such closure, the commercial harvest, sale, trade, barter, or purchase of Atlantic cobia would be prohibited for the remainder of that fishing year. When considering this increase to the commercial quota, and when compared to cobia landings in previous fishing years, NMFS estimates that a commercial in-season closure is still possible as a result of the commercial quota being reached, but expects that any such closure would occur later in the fishing year than occurred under the previous commercial quota.

NMFS may consider additional commercial and recreational regulatory changes to be implemented through rulemaking for Atlantic cobia as described in Amendment 1 and Addendum 1 in future rulemaking.

Comments and Responses

NMFS received nine comments from individuals and a fishery management organization during the public comment period on the proposed rule. NMFS acknowledges the comments in favor of the actions in the proposed rule and agrees with them. Comments received that were outside the scope of the proposed rule are not responded to in this final rule. Comments that opposed the actions contained in the proposed rule are summarized below, along with NMFS' responses.

Comment 1: The commercial quota should not be increased. The Atlantic cobia stock is under high fishing pressure and increasing the commercial quota would hurt the stock's recovery progress.

Response: NMFS disagrees that the commercial quota should not be increased. In 2020, a new SEDAR assessment was completed for Atlantic cobia. The stock assessment indicated that Atlantic cobia was not overfished or undergoing overfishing, and that the allowable harvest could be increased based on updated commercial and recreational catch estimates. In response to the stock assessment, the ASFMC developed Addendum 1 to Amendment 1 and the Interstate FMP. Addendum 1 increased the Atlantic cobia annual total and sector harvest quotas. NMFS does not expect increased commercial catch levels to result in negative impacts to the Atlantic cobia stock.

Comment 2: The commercial quota should not be increased. Commercial harvest limits are constantly increasing while the recreational sector harvest limits keep getting reduced.

Response: NMFS disagrees that the commercial quota shouldn't be increased when compared to recreational harvest. As a result of the latest stock assessment, Addendum 1 increased the harvest quotas for both the commercial and recreational sectors. Addendum 1 also changed sector allocations from 8 percent commercial to 4 percent commercial and from 92 percent recreational to 96 percent recreational. The Atlantic cobia recreational sector continues to be allocated the majority of the available total stock quota. The ASMFC made the change to the sector allocations to account for the revised recreational catch estimates from the Marine Recreational Information Program Fishing Effort Survey. As a result of the updated stock assessment and changes to the sector allocations, the recreational quota increased from 22,142 fish to 76,908 fish and the commercial quota increased from 2,191 fish to 3,204 fish. Therefore the commercial and recreational quota increases are based on the results of the recent assessment and the revised sector allocations as determined by the ASMFC.

Comment 3: In response to the increased Atlantic cobia stock size, the for-hire charter sector should be allowed to keep smaller than 36 inch (91.4 cm) fish or allow 2 fish per person, instead of increasing the commercial quota.

Response: The actions contained in this final rule for the commercial quota increase and revising the process for closing the commercial sector in Federal waters are taken from the request of the ASMFC to NMFS and contained in Amendment 1 and Addendum 1. NMFS acknowledges that within Amendment 1 and Addendum 1, the ASMFC has proposed additional recreational management measures for Federal waters that include size limits and bag and vessel limits based on the existing requirements for each state represented by the ASMFC. NMFS is evaluating those additional management measures and may propose them in a future rulemaking, but at this time changes to size limits and bag and vessel limits are outside the scope of this final rule.

Classification

The NMFS Assistant Administrator has determined that this final rule is consistent with Amendment 1 and Addendum 1, the Interstate FMP, the Atlantic Coastal Act, the applicable provisions of the Magnuson-Stevens Act, and other applicable laws.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification was published in the proposed rule and is not repeated here. No significant issues were raised by public comments related to the economic impacts on small entities, and no changes to this final rule were made in response to public comments. As a result, a final regulatory flexibility analysis was not required and none was prepared.

NMFS finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effective date for this final rule because this rule relieves a restriction by increasing the commercial quota for Atlantic cobia. In addition, delaying implementation of the quota increase is contrary to the public interest. As described in Amendment 1 and Addendum 1, the ASMFC increased the commercial quota based upon the results of the latest stock assessment and is intended to be used in combination with other measures to achieve optimum yield for the stock. Not waiving the 30-day delay in the date of effectiveness of this final rule would result in reduced opportunities for fishermen to harvest the quota and achieve optimum yield this year, and could also result in an early closure of the commercial fishery if the quota is not increased. A closure in 2021 that occurred as a result of the current quota being met, prior to the increased quota being implemented, would not be consistent with the intent of the ASMFC and Amendment 1 and Addendum 1, and is contrary to the public interest. Therefore, a delay in the date of effectiveness of this final rule would diminish the social and economic benefits this rule provides for Atlantic cobia fishermen.

List of Subjects in 50 CFR Part 697

Atlantic, Cobia, Fisheries, Fishing, South Atlantic.

Dated: November 1, 2021.

Carrie Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 697 is amended as follows:

PART 697—ATLANTIC COASTAL FISHERIES COOPERATIVE MANAGEMENT

■ 1. The authority citation for part 697 continues to read as follows:

Authority: 16 U.S.C. 5101 *et seq.*

■ 2. In § 697.28, revise paragraph (f)(1) to read as follows:

§ 697.28 Atlantic migratory group cobia.

* * * * *

(f) * * *

(1) *Commercial quota.* The following quota applies to persons who fish for cobia for commercial purposes—73,116 lb (33,165 kg). If the sum of the cobia landings that are sold, as estimated by the ASMFC, reach or are projected to reach the quota specified in this paragraph (f)(1), then the ASMFC will notify NMFS of the need for a commercial closure of the EEZ. NMFS will then subsequently file a notification with the Office of the Federal Register to prohibit (for commercial purposes) the harvest, sale, trade, barter, or purchase of cobia for the remainder of the fishing year.

* * * * *

[FR Doc. 2021–24172 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 213
Monday, November 8, 2021

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 959 and 980

[Docket No. AMS–SC–21–0003; SC21–959–2 PR]

Onions Grown in South Texas and Imported Onions; Termination of Marketing Order 959 and Change in Import Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; Reopening of comment period.

SUMMARY: The Agricultural Marketing Service (AMS) is providing an additional thirty (30) days for public comments on a proposed rule that would terminate the Federal marketing order regulating the handling of onions grown in South Texas and the rules and regulations issued thereunder. A corresponding change would be made to the onion import regulation as required under section 8e of the Agricultural Marketing Agreement Act of 1937. Reopening the comment period gives interested persons an additional opportunity to comment on the proposed termination.

DATES: The comment period for the proposed rule published on August 5, 2021, at 86 FR 42748, is reopened. Comments must be received by December 8, 2021.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be submitted to the Docket Clerk electronically by Email: *MarketingOrderComment@usda.gov* or internet: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register** and can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposal will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Abigail Campos, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Abigail.Campos@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request additional information on this Notice by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: A proposed rule was published in the **Federal Register** on August 5, 2021 (86 FR 42748). The rulemaking proposed to terminate the Federal marketing order regulating the handling of onions grown in South Texas (Order) and the rules and regulations issued thereunder. Furthermore, Section 8e of the Agricultural Marketing Agreement Act of 1937 (Act) provides that when certain domestically produced commodities, including onions, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. Because this proposed rule would terminate regulations for domestically produced onions, a corresponding change to the import regulations would also be required.

The proposed rule is based on the results of a continuance referendum in which producers failed to support the continuation of the Order. USDA's analysis of comments will help determine whether termination of this program would be appropriate and whether the Order is favored by industry producers.

During the initial comment period, AMS received a request to extend the comment period for an additional 30 days to allow those affected by the rulemaking to weigh in on the proposed termination of the Order.

After reviewing the request, USDA is reopening the comment period for 30 days. This will provide interested persons more time to review the proposed rule, perform a more complete analysis, and prepare information in writing to support their comments. Accordingly, the period in which to file written comments is reopened until December 8, 2021.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–24301 Filed 11–5–21; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 53

[NRC–2019–0062]

RIN 3150–AK31

Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Availability of preliminary proposed rule language; reopening of comment period.

SUMMARY: On November 6, 2020, the U.S. Nuclear Regulatory Commission (NRC) solicited comments on preliminary proposed rule language for a risk-informed, technology-inclusive framework for reactor licensing. The public comment period closed on November 5, 2021. The NRC has decided to reopen the public comment period until January 31, 2022, to allow more time for members of the public to develop and submit their comments.

DATES: The comment period for the **Federal Register** document published on November 6, 2020 (85 FR 71002), is reopened and now closes on January 31, 2022. Comments received after this date will be considered in the development of the proposed rule if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments on preliminary rule language by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search

for Docket ID NRC–2019–0062. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.

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

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–3874; email: *Robert.Beall@nrc.gov;* or William Reckley, Office of Nuclear Reactor Regulation, telephone: 301–415–7490; email: *William.Reckley@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0062 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0062.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for the preliminary proposed rule text is ML20289A534.

• *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2019–0062 in your comment submission.

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

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

II. Discussion

On November 6, 2020 (85 FR 71002), the NRC solicited comments on preliminary proposed rule language for a risk-informed, technology-inclusive framework for reactor licensing. The public comment period closed on November 5, 2021. The NRC has decided to reopen the public comment period on this document until January 31, 2022, to allow more time for members of the public to submit their comments.

Dated: November 2, 2021.

For the Nuclear Regulatory Commission.

John R. Tappert,

Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–24329 Filed 11–5–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0960; Project Identifier 2019–CE–021–AD]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited (Type Certificate Previously Held by Bombardier, Inc., de Havilland, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 80–13–10, AD 80–13–12 R1, and AD 2008–03–01, which apply to certain de Havilland (type certificate now held by Viking Air Limited) Model DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes. AD 80–13–10 requires repetitively inspecting the main landing gear (MLG) legs for cracks and corrosion. AD 80–13–12 R1 requires repetitively inspecting each engine nacelle lower longeron for cracks and buckling. AD 2008–03–01 requires incorporating inspections, modifications, and life limits of certain structural components into the aircraft maintenance program. Since the FAA issued those ADs, new and more restrictive airworthiness limitations have been issued for certain structural components. This proposed AD would require incorporating into maintenance records new or revised life limits, modification limits, and inspection or overhaul intervals. 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 December 23, 2021.

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

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.

• *Fax:* (202) 493–2251.

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

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; phone: (North America) (800) 663–8444; fax: (250) 656–0673; email: *technical.support@vikingair.com;* website: *https://www.vikingair.com/support/service-bulletins.* You may view this service information at the Airworthiness Products Section, Operational Safety Branch, FAA, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0960; 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 MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aviation Safety Engineer, New York ACO Branch, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2021–0960; Project Identifier 2019–CE–021–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Aziz Ahmed, Aviation Safety Engineer, New York ACO Branch, 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 FAA issued AD 80–13–10, Amendment 39–3812 (45 FR 43155, June 26, 1980) (AD 80–13–10) for de Havilland (type certificate now held by Viking Air Limited) Model ''DHC–6 type'' airplanes with certain MLG legs. AD 80–13–10 was prompted by several incidents involving collapse of the MLG. AD 80–13–10 requires repetitively inspecting the weld juncture at the Y-joint of the MLG legs for cracks and corrosion. The FAA issued AD 80–13–10 to prevent failure of the MLG legs at the Y-joint weld, which could result in wing damage during taxiing operations.

The FAA issued AD 80–13–12 R1, Amendment 39–4135 (46 FR 31251, June 15, 1981) (AD 80–13–12 R1) for certain serial-numbered de Havilland (now Viking Air Limited) Model ''DHC–6 type'' airplanes with intermediate or high floatation tires, skis, or floats. AD 80–13–12 R1 was prompted by reports of cracks or buckling on the engine nacelle lower longerons. AD 80–13–12 R1 requires repetitively inspecting each engine nacelle lower longeron for cracks and buckling. The FAA issued AD 80–13–12 R1 to prevent possible failure of the engine nacelle lower longerons due to cracking or buckling.

The FAA issued AD 2008–03–01, Amendment 39–15350 (73 FR 5729, January 31, 2008) (AD 2008–03–01), for all Viking Air Limited Model DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes. AD 2008–03–01 was prompted by structural evaluations of the DHC–6 series airplanes that showed the service life limits and inspection schedules needed to be revised. AD 2008–03–01 was based on Canadian AD CF–2000–14, dated May 25, 2000 (AD CF–2000–14), issued by Transport Canada, which is the aviation authority for Canada. AD 2008–03–01 requires incorporating the inspections, modifications, and life limits (retirement) of certain structural components, as contained in Revision 5 of the DHC–6 Product Support Manual (PSM) 1–6–11, into the aircraft maintenance program. The FAA issued AD 2008–03–01 to maintain the structural integrity of the airplane.

Actions Since AD 2008–03–01 Was Issued

Since the FAA issued AD 2008–03–01, Transport Canada has superseded AD CF–2000–14 and issued Canadian AD CF–2019–02, dated January 9, 2019 (referred to after this as ''the MCAI''). The MCAI applies to all Viking Air Limited (formerly de Havilland) Model DHC–6 series 1, DHC–6 series 100, DHC–6 series 110, DHC–6 series 200, DHC–6 series 210, DHC–6 series 300, DHC–6 series 310, DHC–6 series 320, and DHC–6 series 400 airplanes. The MCAI states:

> The airworthiness limitations for DHC–6 aeroplanes are defined and published in the Viking Air Ltd. (Viking) Airframe Airworthiness Limitations Manual, Product Support Manual (PSM) 1–6–11, approved by Transport Canada. The instructions contained in PSM 1–6–11 have been identified as mandatory actions for continued airworthiness. Failure to comply with those instructions could result in an unsafe condition.
>
> Viking Air Ltd. published Revision 9 of PSM 1–6–11 earlier in 2018. Revision 9 of PSM 1–6–11, dated 30 April 2018, includes some new and/or more restrictive limitations than those contained in Revision 5. For the reason described above, this [Transport Canada] AD requires implementation of the actions specified in PSM 1–6–11 Revision 9.
>
> The compliance requirements for several of the tasks in PSM 1–6–11 were previously a range of flight hours and flight cycles. With Revision 9 of PSM 1–6–11, the range-based requirements have been changed to specific flight hours and flight cycle limits. This [Transport Canada] AD provides a phase-in allowance for those limitations so that operators will have the opportunity to schedule the modifications and inspections required by the limitations. The phase-in allowances are intended to mitigate the impact of changing from compliance ranges to compliance limits for aeroplanes that are approaching or have exceeded the limits on the effective date of the [Transport Canada] AD.
>
> Revision 9 of PSM 1–6–11 also includes some airworthiness limitations that were previously contained in service bulletins (SB) or other PSMs. Some of those limitations were mandated by [Transport Canada] ADs, specifically AD CF–80–06, CF–81–07R4 and CF–95–12. Because the affected limitations will now be controlled in PSM 1–6–11, the above mentioned [Transport Canada] ADs are superseded by this [Transport Canada] AD.
>
> The following are new tasks in PSM 1–6–11 Revision 9:
>
> 1. Task 27–007 Replacement of flight control pulleys at Fuselage Station (FS) 270.
> 2. Tasks 32–001 and 32–002 Overhaul of main landing gear leg. There is an associated requirement to ensure that each affected part has been assigned a unique serial number.
> 3. Task 53–006 Inspection of the skin flange of machined frame at FS 239.
> 4. Tasks 54–003 to 54–010 Inspection of nacelle longerons.

5. Tasks 57–039 to 57–041 Inspection for wing upper skin disbond.

Task 27–004 Replacement of flight control cables after spillage of corrosive materials in PSM 1–6–11 was limited to landplane configurations in previous revisions of PSM 1–6–11 but is now applicable to all configurations.

The intent of the word ''airframe'' in PSM 1–6–11 Revision 9 is to include fuselage, nacelles, struts, interiors, cowlings, fairings, airfoils, landing gear and their controls. The airframe life limitation in PSM 1–6–11 Revision 9 is not intended to apply to components such as those in the fuel, electrical and hydraulic systems that are occasionally transferred from one aeroplane to another and may be salvaged from an aeroplane that is retired from service for use on an in-service aeroplane. PSM 1–6–13 defines current airworthiness limitations for DHC–6 avionics that are not addressed in this [Transport Canada] AD.

Model DHC–6–400 airplanes were type certificated after AD CF–2000–14 was issued and are subject to the same unsafe condition. You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0960.

Related Service Information Under 1 CFR Part 51

The FAA reviewed DHC–6 Twin Otter PSM 1–6–11, Airframe Airworthiness Limitations Manual, Revision 9, dated April 30, 2018. The service information contains airworthiness limitations for certain structural components. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require incorporating into maintenance records new or revised life limits, modification limits, and inspection or overhaul intervals. This proposed AD would also allow a ''phase-in'' compliance period for the initial completion of certain tasks.

ADs Mandating Airworthiness Limitations

The FAA has previously mandated airworthiness limitations by issuing ADs that require revising the airworthiness limitation section (ALS) of the existing maintenance manual or instructions for continued airworthiness to incorporate new or revised inspections and life limits. This proposed AD, however, would require incorporating new or revised inspections and life limits into the maintenance records required by 14 CFR 91.417(a)(2) or 135.439(a)(2) for your airplane. The FAA does not intend this as a substantive change. Requiring incorporation of the new ALS requirements into the maintenance records, rather than requiring individual repetitive inspections and replacements, allows operators to record AD compliance once after updating the maintenance records, rather than recording compliance after every inspection and part replacement.

Differences Between This Proposed AD and the MCAI

The MCAI applies to Viking Air Limited Model DHC–6 series 110, DHC–6 series 210, DHC–6 series 310, and DHC–6 series 320, and this proposed AD would not because these models do not have an FAA type certificate. Transport Canada Models DHC–6 series 1, DHC–6 series 100, DHC–6 series 200, DHC–6 series 300, and DHC–6 series 400 airplanes correspond to FAA Model DHC–6–1, DHC–6–100, DHC–6–200, DHC–6–300, and DHC–6–400 airplanes, respectively.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 33 airplanes of U.S. registry.

The FAA also estimates that it would take about 1 work-hour per airplane to incorporate life limits, modification limits, and inspection or overhaul intervals, into maintenance records. The average labor rate is $85 per work-hour.

Based on these figures, the FAA estimates the cost of the proposed AD on U.S. operators to be $2,805 or $85 per airplane.

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 80–13–10, Amendment 39–3812 (45 FR 43155, June 26, 1980); Airworthiness Directive 80–13–12 R1, Amendment 39–4135 (46 FR 31251, June 15, 1981); and Airworthiness Directive 2008–03–01, Amendment 39–15350 (73 FR 5729, January 31, 2008); and

■ b. Adding the following new airworthiness directive:

Viking Air Limited (Type Certificate Previously Held by Bombardier, Inc., de

Havilland, Inc.): Docket No. FAA–2021–0960; Project Identifier 2019–CE–021–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 23, 2021.

(b) Affected ADs

This AD replaces the ADs specified in paragraphs (b)(1) through (3) of this AD.

(1) AD 80–13–10, Amendment 39–3812 (45 FR 43155, June 26, 1980).

(2) AD 80–13–12 R1, Amendment 39–4135 (46 FR 31251, June 15, 1981).

(3) AD 2008–03–01 Amendment 39–15350 (73 FR 5729, January 31, 2008).

(c) Applicability

This AD applies to Viking Air Limited (type certificate previously held by Bombardier, Inc., de Havilland, Inc.) Model DHC–6–1, DHC–6–100, DHC–6–200, DHC–6–300, and DHC–6–400 airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 0500, Time Limits.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and address an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as failure to comply with new and more restrictive airworthiness limitations, including tasks where range-based requirements have been changed to specific hours time-in-service (TIS) and flight cycle limits. The FAA is issuing this AD to prevent loss of structural integrity of certain parts. The unsafe condition, if not addressed, could result in loss of control of the airplane.

(f) Compliance

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

(g) Maintenance and Life Limits

(1) Within 30 days after the effective date of this AD, incorporate into the maintenance records required by 14 CFR 91.417(a)(2) or 135.439(a)(2) for your airplane the life limits, modification limits, and inspection or overhaul intervals in DHC–6 Twin Otter PSM 1–6–11, Airframe Airworthiness Limitations Manual, Revision 9, dated April 30, 2018 (PSM 1–6–11 Rev9).

(2) Before further flight after revising the maintenance records as required by paragraph (g)(1) of this AD, except as allowed under paragraph (h) of this AD, remove from service each part that has reached or exceeded its life limit and modify each part that has reached or exceeded its modification limit.

(3) Before further flight after revising the maintenance records as required by paragraph (g)(1) of this AD, except as allowed under paragraph (h) of this AD, inspect or overhaul each part that has reached or exceeded its inspection or overhaul interval.

(h) Phase-In Period

The following phase-in periods are allowed to comply with the initial tasks in PSM 1–6–11 Rev9.

(1) Task 27–007: For any pulley that has been in service for 48 or more months on the effective date of this AD, replace the pulley within 12 months after the effective date of this AD.

(2) Tasks 32–001 and 32–002:

(i) For any main landing gear (MLG) leg that, on the effective date of this AD, has not been marked with a new serial number as specified in Viking DHC–6 Twin Otter Technical Bulletin V6/00063: Within 6 months after the effective date of this AD, inspect and serialize the MLG leg. The absence of a serial number indicates that the initial inspection of the landing gear leg has not previously been accomplished.

(ii) For all other MLG legs, overhaul the MLG leg within 60 months after the last overhaul.

(3) Tasks 57–006, 57–007, 57–010, 57–011, 57–013, and 57–014:

(i) For any wing that on the effective date of this AD has accumulated more than 16,000 hours total TIS or 32,000 total flight cycles but less than 17,000 hours total TIS or less than 34,000 total flight cycles, accomplish the task within 1,000 hours TIS or 2,000 flight cycles, whichever occurs first after the effective date of this AD.

(ii) For any wing that on the effective date of this AD has accumulated 17,000 or more hours total TIS or 34,000 or more total flight cycles, accomplish the task before accumulating 18,000 hours total TIS or 36,000 total flight cycles, or within 60 months after the effective date of this AD, whichever occurs first.

(4) Tasks 57–018, 57–019, 57–022, 57–023, 57–026, 57–027, 57–030, and 57–031:

(i) For any wing that on the effective date of this AD has accumulated more than 11,000 hours total TIS or 22,000 total flight cycles but less than 12,000 hours total TIS or less than 24,000 total flight cycles, accomplish the task within 1,000 hours TIS or 2,000 flight cycles, whichever occurs first after the effective date of this AD.

(ii) For any wing that on the effective date of this AD has accumulated 12,000 or more hours total TIS or 24,000 or more total flight cycles, accomplish the task before accumulating 13,000 hours total TIS or 26,000 total flight cycles or within 60 months after the effective date of this AD, whichever occurs first.

(5) Tasks 57–039 to 57–041 inclusive: For any wing that on the effective date of this AD has more than 20 years since the date of manufacture and has not previously been inspected in accordance with Viking Service Bulletin V6/0018, inspect the wing upper surface within 120 days after the effective date of this AD.

(i) No Alternative Actions or Intervals

After the maintenance records have been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD.

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

(k) Related Information

(1) For more information about this AD, contact Aziz Ahmed, Aviation Safety Engineer, New York ACO Branch, FAA,1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov*.

(2) Refer to Transport Canada AD CF–2019–02, dated January 9, 2019, for more information. You may examine the Transport Canada AD in the AD docket at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2021–0960.

(3) For service information identified in this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; phone: (North America) (800) 663–8444; fax: (250) 656–0673; email: *technical.support@vikingair.com;* website: *https://www.vikingair.com/support/service-bulletins.* You may view this service information at the Airworthiness Products Section, Operational Safety Branch, FAA, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on November 1, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24102 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0919; Airspace Docket No. 21–ASO–32]

RIN 2120–AA66

Proposed Amendment of United States Area Navigation (RNAV) Route T–215; Central United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend United States Area Navigation (RNAV) route T–215 in the central United States due to the decommissioning of the Holston Mountain, TN, (HMV) VHF Omnidirectional Range Tactical Air Navigation (VORTAC), and the Hazard, KY, (AZQ) Distance Measuring Equipment (DME) in support of the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) program. Additionally, this action would extend T–215 to the north and south of its current limits to expand the availability of RNAV in the National Airspace System (NAS).

DATES: Comments must be received on or before December 23, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1 (800) 647–5527 or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0919; Airspace Docket No. 21–ASO–32 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV routes in the NAS, increase airspace capacity, and reduce complexity in high air traffic volume areas.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2021–0919; Airspace Docket No. 21–ASO–32 and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0919; Airspace Docket No. 21–ASO–32.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRM's

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.* You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend RNAV route T–215 by extending the route further to the north and southeast in the central United States. This action is necessary due to the planned decommissioning of the Holston Mountain, TN, (HMV) VORTAC, and the Hazard, KY, (AZQ) DME.

T–215: T–215 currently extends between the Holston Mountain, TN, VORTAC, and the GAMKE, IN, waypoint (WP). The proposed amendment would include replacing the Holston Mountain, TN, VORTAC with the HORAL, TN, WP, and replacing the Hazard, KY, DME with the DACEL, KY, WP. The route would be extended south of the HORAL WP to the BURGG, SC, WP. Additionally, the route would be extended to the north of the GAMKE, IN, WP ending at the CPTON, IL, WP, which is approximately 15 nautical miles east of the Bradford, IL, (BDF) VORTAC. The HILTO, VA, Fix; FLENR, VA, WP; and RISTE, KY, WP, are not needed for defining the track of T–215 so they would be removed from the route legal description. In addition, the HUGEN, KY, Fix would be removed from the route because it does not denote a route turn point. Because a VOR is not a required component for navigating on T–215, removal of the Holston Mountain VORTAC would not affect the alignment or navigation along T–215.

As amended, T–215 would extend between the BURGG, SC, WP, and the CPTON, IL, WP. The full route legal description is listed in ''The Proposed Amendment'' section, below.

These changes would expand the availability of RNAV to reduce the NAS dependency on ground based navigational systems and assist with the transition to a more efficient Performance Based Navigation route structure.

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

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

Regulatory Notices and Analyses

The FAA has determined that this 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 FAA final regulatory action.

List 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 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021 and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–215 BURGG, SC TO CPTON, IL [AMENDED]

BURGG, SC	WP	(Lat. 35°02′00.55″ N, long. 081°55′36.86″ W)
GENOD, NC	FIX	(Lat. 35°33′06.04″ N, long. 081°56′57.05″ W)
HORAL, TN	WP	(Lat. 36°26′13.99″ N, long. 082°07′46.48″ W)
DACEL, KY	WP	(Lat. 37°23′10.68″ N, long. 083°14′52.13″ W)
Lexington, KY (HYK)	VOR/DME	(Lat. 37°57′58.86″ N, long. 084°28′21.06″ W)
GAMKE, IN	WP	(Lat. 38°46′12.99″ N, long. 085°14′35.37″ W)
MILAN, IN	WP	(Lat. 39°21′21.98″ N, long. 085°19′00.63″ W)
DEEKS, IN	WP	(Lat. 40°12′38.37″ N, long. 085°58′05.38″ W)
BONOY, IN	FIX	(Lat. 40°30′24.11″ N, long. 086°01′16.88″ W)
CLEFT, IN	WP	(Lat. 41°04′51.95″ N, long. 086°02′29.28″ W)
MAPPS, IN	WP	(Lat. 41°10′53.94″ N, long. 086°56′32.63″ W)
CPTON, IL	WP	(Lat. 41°06′51.57″ N, long. 089°11′58.93″ W)

* * * * *

Issued in Washington, DC, on October 27, 2021.

Michael R. Beckles,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–24279 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0940; Airspace Docket No. 21–ASO–12]

RIN 2120–AA66

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend 11 low altitude United States Area Navigation (RNAV) T-routes, and remove 1 T-route, in support of the South-Central FL Metroplex Project. The proposed route changes would expand the availability of RNAV routing in support of transitioning the National Airspace System (NAS) from ground-based to satellite-based navigation.

DATES: Comments must be received on or before December 23, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0940; Airspace Docket No. 21–ASO–12 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV in the south Florida United States and improve the efficient flow of air traffic within the NAS by lessening the dependency on ground-based navigation.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2021–0940; Airspace Docket No. 21–ASO–12) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0940; Airspace Docket No. 21–ASO–12.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.* You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

List of Acronyms

For reference, the following acronyms are used in this NPRM:

IFR—Instrument Flight Rules
NAVAID—Navigational Aid
RNAV—Area Navigation
VOR—VHF Omnidirectional Range
VOR/DME—VHF Omnidirectional Range/Distance Measuring Equipment
VORTAC—VHF Omnidirectional Range/Tactical Air Navigation
WP—RNAV Waypoint

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to modify 11 low altitude RNAV T-routes, and remove one T-route, in support of the South-Central FL Metroplex Project.

T–207: T–207 currently extends between the Ormond Beach, FL, (OMN) VORTAC and the Waycross, GA, (AYS) VORTAC. This action proposes to realign T–207 by moving the starting point from the Ormond Beach VORTAC to the FOXAM, FL, waypoint (WP), which is approximately 15 nautical miles (NM) north of the Ormond Beach VORTAC. The CARRA, FL, and the MONIA, FL, Fixes would be removed from the route, and the segments between the CARRA Fix and the Waycross, GA, (AYS) VORTAC would also be removed. Instead, T–207 would begin at the FOXAM, FL, WP, then proceed to the MMKAY, FL WP, then to a new end point at the WALEE, FL, WP (located east of the Gators, FL, (GNV) VORTAC).

T–208: T–208 currently extends between the WALEE, FL, WP, and the SHANC, FL, WP. This action would remove the WALEE, FL, and the MMKAY, FL, WPs from the route. The SIROC, GA, WP would be added as the new start point of the route. The SAHND, FL, WP would be added between the SIROC, GA, and the FOXAM, FL, WPs. After the FOXAM, FL, WP, T–208 would proceed to the SHANC, FL, Fix, as currently depicted on the IFR Low Altitude Chart.

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

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

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

T–339: T–339 currently extends between the KARTR, FL, Fix and the ODDEL, FL, Fix. This change would remove the KARTR Fix from the route. The start point would be moved approximately 25 NM to the southeast

of the KARTR Fix to the existing CARNU, FL, Fix. From the CARNU Fix, T–339 would proceed to the DEEDS, FL, Fix, and then proceed to the end point at the ODDEL, FL, Fix as currently charted.

T–341: T–341 currently extends between the MEAGN, FL, WP, and the MARQO, FL WP. The FAA proposes to insert additional WPs along the route as follows. The YELLZ, FL, WP would be inserted between the CUSEK, FL, WP and the WEZER, FL, WP. The DULFN, FL, OMMNI, FL, and WHOOU, FL WPs would be added between the VARSE, FL, and the MARQO, FL, WPs.

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

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

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

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

T–353: T–353 currently extends between the FEBRO, FL, WP and the ASTOR, FL, Fix.

This action would remove the ASTOR, FL, Fix from the route and establish a new end point for the route at the STARY, GA, Fix (located 18 NM northeast of the Brunswick, GA, (SSI) VORTAC. The COBOK, FL, Fix and the SUBER, FL, Fix would be added between the FOXAM, FL, WP, and the STARY, GA, Fix. This would result in the track of T–353 north of the FOXAM WP being shifted to the east of its current alignment. Additionally, moving the end point of the route from the ASTOR Fix to the STARY Fix would provide approximately 80 NM of additional RNAV routing to the NAS.

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

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

Regulatory Notices and Analyses

The FAA has determined that this 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 FAA final regulatory action.

List 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 14 CFR 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

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

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

* * * * * * *

T–208 SIROC, GA to SHA N, FL [Amended]

SIROC, GA	WP	(Lat. 31°03′02.32″ N, long. 081°26′45.89″ W)
SAHND, FL	WP	(Lat. 30°25′45.91″ N, long. 081°24′34.99″ W)
FOXAM, FL	WP	(Lat. 29°33′37.73″ N, long. 081°09′37.84″ W)
SUUGR, FL	WP	(Lat. 29°19′40.38″ N, long. 081°07′20.79″ W)
SMYRA, FL	FIX	(Lat. 29°00′19.48″ N, long. 080°59′34.51″ W)
OAKIE, FL	FIX	(Lat. 28°51′04.26″ N, long. 080°55′52.35″ W)
MALET, FL	FIX	(Lat. 28°41′29.90″ N, long. 080°52′04.30″ W)
TICCO, FL	FIX	(Lat. 28°31′00.50″ N, long. 080°47′52.80″ W)
INDIA, FL	FIX	(Lat. 28°26′04.19″ N, long. 080°45′55.25″ W)
DIMBY, FL	WP	(Lat. 28°04′52.54″ N, long. 080°37′37.61″ W)
VALKA, FL	FIX	(Lat. 27°55′06.06″ N, long. 080°34′17.17″ W)
SULTY, FL	WP	(Lat. 27°48′12.41″ N, long. 080°32′59.17″ W)
WIXED, FL	WP	(Lat. 27°41′24.86″ N, long. 080°29′56.56″ W)

CLEFF, FL	WP	(Lat. 27°00′03.31″ N, long. 080°32′38.27″ W)
DURRY, FL	WP	(Lat. 26°43′46.96″ N, long. 080°24′09.25″ W)
BOBOE, FL	WP	(Lat. 26°28′48.72″ N, long. 080°23′05.23″ W)
SHANC, FL	FIX	(Lat. 26°18′51.14″ N, long. 080°20′00.16″ W)

* * * * * * *

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

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

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

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

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

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

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

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T–341 MEAGN FL to MARQO, FL [Amended]

MEAGN FL	WP	(Lat. 26°14′17.20″ N, long. 080°47′23.64″ W)
ZAGPO, FL	WP	(Lat. 26°23′47.41″ N, long. 080°57′25.83″ W)
CUSEK, FL	WP	(Lat. 26°51′38.79″ N, long. 081°23′17.37″ W)
YELLZ, FL	WP	(Lat. 27°51′36.18″ N, long. 081°56′34.16″ W)
WEZER, FL	WP	(Lat. 28°02′26.59″ N, long. 082°02′39.60″ W)
VARZE, FL	WP	(Lat. 28°16′25.85″ N, long. 082°01′44.51″ W)
DULFN FL	WP	(Lat. 28°37′02.05″ N, long. 082°06′24.33″ W)
OMMNI, FL	WP	(Lat. 28°51′29.29″ N, long. 082°09′41.75″ W)
WHOOU, FL	WP	(Lat. 29°51′25.91″ N, long. 082°23′30.65″ W)
MARQO, FL	WP	(Lat. 30°30′53.57″ N, long. 082°32′45.62″ W)

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

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

* * * * * * *

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

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

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

SHANC, FL	FIX	(Lat. 26°18′51.14″ N, long. 080°20′00.16″ W)
BOBOE, FL	WP	(Lat. 26°28′48.72″ N, long. 080°23′05.23″ W)
DURRY, FL	WP	(Lat. 26°43′46.96″ N, long. 080°24′09.25″ W)
CLEFF, FL	WP	(Lat. 27°00′03.31″ N, long. 080°32′38.27″ W)
BAIRN FL	FIX	(Lat. 27°56′52.37″ N, long. 081°06′54.35″ W)
ODDEL, FL	FIX	(Lat. 28°05′45.51″ N, long. 081°10′10.24″ W)

SABOT, FL	FIX	(Lat. 28°15′05.10″ N, long. 081°13′37.16″ W)
CROPY, FL	FIX	(Lat. 28°47′32.71″ N, long. 081°21′35.38″ W)
KIZER, FL	FIX	(Lat. 28°55′26.00″ N, long. 081°22′17.83″ W)
GUANO, FL	FIX	(Lat. 29°05′58.73″ N, long. 081°23′18.93″ W)
MRUTT, FL	WP	(Lat. 29°12′12.40″ N, long. 081°23′55.50″ W)
FOXAM, FL	WP	(Lat. 29°33′37.73″ N, long. 081°09′37.84″ W)
SEBAG, FL	FIX	(Lat. 29°49′04.24″ N, long. 081°12′34.72″ W)

* * * * * * *

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

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

* * * * * * *

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

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

* * * * *

Issued in Washington, DC, on October 29, 2021.

Michael R. Beckles,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–24191 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0974; Airspace Docket No. 21–AEA–15]

RIN 2120–AA66

Proposed Amendment of United States Area Navigation (RNAV) Routes T–212, T–216, T–218, and T–221; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend United States Area Navigation (RNAV) routes T–212, T–216, T–218, and T–221 in the eastern United States. The proposed route changes would add RNAV waypoints (WP) to replace VHF Omnidirectional Range (VOR) navigation aids (NAVAIDS) that are scheduled for decommissioning under the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before December 23, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0974; Airspace Docket No. 21–AEA–15 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV in the eastern United States and improve the efficient flow of air traffic within the NAS by lessening the dependency on ground-based navigation.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2021–0974; Airspace Docket No. 21–AEA–15) and be submitted in triplicate

to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0974; Airspace Docket No. 21–AEA–15.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.* You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend RNAV routes T–212, T–216, T–218, and T–221 in the eastern United States. The changes would consist of adding RNAV WPs to replace navigation aids that are scheduled for decommissioning. The changes would not affect navigation along the routes.

T–212: T–212 currently extends between the RASHE, PA, Fix and the Putnam, CT, (PUT) VOR/Distance Measuring Equipment (DME). Due to planned decommissioning of the Wilkes Barre, PA, (LVZ) VORTAC, it would be replaced by the WILKES, PA, WP, (located 60 feet northeast of the Wilkes Barre VORTAC. The Putnam, CT (PUT) VOR/DME would be replaced by the PUTNM, CT, WP (located 1.5 feet southwest of the Putnam VOR/DME).

T–216: T–216 currently extends between the Phillipsburg, PA, (PSB) VORTAC and the Nantucket, MA, (ACK) VOR/DME. Because the Williamsport, PA, (FQM) VOR/DME is planned for decommissioning, it would be replaced by the LYKOM, PA, WP, (located 60 feet southwest of the Williamsport VOR/DME). The currently published description of T–216 contains an exclusion of the airspace within restricted area R–4105. R–4105 was revoked by the FAA on November 17, 2014. Therefore, the exclusion will be removed from the route description.

T–218: T–218 currently extends between the Stonyfork, PA, (SFK) VOR/DME, and the Sparta, NJ, (SAX) VORTAC. The Stonyfork VOR/DME would be replaced by the DLMAR, PA, WP, (located 60 feet southeast of the Stonyfork VOR/DME). As amended, T–218 would extend between the DELMAR WP and the Sparta VORTAC.

T–221: T–221 currently extends between the MAZIE, PA, Fix and the Binghamton, NY, (CFB) VOR/DME. This action would replace the Allentown, PA, (FJC) VOR/DME with the EESTN, PA, WP (located 60 feet northeast of the Allentown VOR/DME).

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

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

Regulatory Notices and Analyses

The FAA has determined that this 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 FAA final regulatory action.

List 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 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–212 RASHE, PA TO PUTNM, CT [AMENDED]

RASHE, PA	FIX	(Lat. 40°40′36.04″ N, long. 077°38′38.94″ W)
SELINSGROVE, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
DIANO, PA	FIX	(Lat. 41°00′01.99″ N, long. 076°13′33.78″ W)
WLKES, PA	WP	(Lat. 41°16′22.57″ N, long. 075°41′21.60″ W)
LAAYK, PA	FIX	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
WEETS, NY	FIX	(Lat. 41°51′26.98″ N, long. 074°11′51.51″ W)
NELIE, CT	FIX	(Lat. 41°56′27.64″ N, long. 072°41′18.88″ W)
PUTNM, CT	WP	(Lat. 41°57′19.65″ N, long. 071°50′38.76″ W)

* * * * * * *

T–216 PHILIPSBURG, PA (PSB) TO NANTUCKET, MA (ACK) [AMENDED]

PHILIPSBURG, PA (PSB)	VORTAC	(Lat. 40°54′58.53″ N, long. 077°59′33.78″ W)
LYKOM, PA	WP	(Lat. 41°20′18.75″ N, long. 076°46′30.30″ W)
ELEXY, PA	WP	(Lat. 41°25′53.71″ N, long. 076°07′35.20″ W)
LAAYK, PA	FIX	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
HELON, NY	FIX	(Lat. 41°40′02.72″ N, long. 074°16′49.52″ W)
KINGSTON, NY (IGN)	VOR/DME	(Lat. 41°39′55.62″ N, long. 073°49′20.01″ W)
MOONI, CT	FIX	(Lat. 41°37′53.28″ N, long. 073°19′19.43″ W)
HARTFORD, CT (HFD)	VOR/DME	(Lat. 41°38′27.98″ N, long. 072°32′50.70″ W)
GROTON, CT (GON)	VOR/DME	(Lat. 41°19′49.45″ N, long. 072°03′07.14″ W)
SANDY POINT, RI (SEY)	VOR/DME	(Lat. 41°10′02.77″ N, long. 071°34′33.91″ W)
NANTUCKET, MA (ACK)	VOR/DME	(Lat. 41°16′54.79″ N, long. 070°01′36.16″ W)

* * * * * * *

T–218 DLMAR, PA TO SPARTA, NJ [AMENDED]

DLMAR, PA	WP	(Lat. 41°41′42.56″ N, long. 077°25′11.02″ W)
LAAYK, PA	FIX	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
SPARTA, NJ (SAX)	VORTAC	(Lat. 41°04′03.15″ N, long. 074°32′17.91″ W)

* * * * * * *

T–221 MAZIE, PA TO BINGHAMTON, NY [AMENDED]

MAZIE, PA	FIX	(Lat. 40°19′19.55″ N, long. 075°06′35.28″ W)
EESTN, PA	WP	(Lat. 40°43′36.50″ N, long. 075°27′16.55″ W)
LAAYK, PA	FIX	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
BINGHAMTON, NY (CFB)	VOR/DME	(Lat. 42°09′26.96″ N, long. 076°08′11.30″ W)

* * * * * * *

Issued in Washington, DC, on October 29, 2021.

Michael R. Beckles,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–24174 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 328

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 120

[FRL–6027.4–05–OW]

Deadline Extension for Regional Roundtable Discussions Regarding ''Waters of the United States''

AGENCY: Department of the Army, Corps of Engineers, Department of Defense; and Environmental Protection Agency (EPA).

ACTION: Notice of events; extension of deadline request for nominations.

SUMMARY: On October 13, 2021, the U.S. Environmental Protection Agency (EPA) and the U.S. Department of the Army (hereafter, ''the agencies'') signed a **Federal Register** publication and publicly announced a process for stakeholders to submit nomination letters with a slate of participants to potentially be selected as one of ten geographically focused roundtables to provide input on the regional implications of ''waters of the United States'' (WOTUS) under the Clean Water Act. The intent for each regional roundtable is to engage individuals representing diverse perspectives in meaningful dialogue on the definition of ''waters of the United States.'' This **Federal Register** document was published on October 25, 2021. In response to robust interest in these roundtables, the agencies are extending the deadline for nominations to be submitted to 11:59 p.m. Eastern Standard Time on December 1, 2021. In addition, the agencies are providing certain clarifications regarding the nomination process.

DATES: Nomination letters for the roundtables must be received on or before 11:59 p.m. Eastern Standard Time on December 1, 2021. As a result of the deadline extension, EPA anticipates roundtables will be held in early 2022. Specific dates will be coordinated with selected nominees based on availability. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information.

FOR FURTHER INFORMATION CONTACT: Kate Balasa, Office of Water, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (312) 886–6027; email address: *WOTUS-outreach@epa.gov*, or Stacey Jensen, Office of the Assistant Secretary of the Army for Civil Works, Department of the Army, 108 Army Pentagon, Washington, DC 20310–0104; telephone number: (703) 459–6026; email address: *usarmy.pentagon.hqda-asa-cw.mbx.asa-cw-reporting@mail.mil.*

SUPPLEMENTARY INFORMATION: In response to robust interest in and certain inquiries regarding the regional roundtables on ''waters of the United States'' announced on October 13, 2021, the agencies are extending the deadline for submitting nominations and providing clarifications.

The **Federal Register** publication published on October 25, 2021 (86 FR 58829) states: ''On June 9, 2021, [the agencies] announced their intent to revise the definition of 'waters of the United States' under the Clean Water Act through two rulemakings—first, a foundational rule that will propose to restore longstanding protections, and a second rulemaking process that builds on that regulatory foundation. . . . The

agencies are seeking input on a durable definition of 'waters of the United States' not limited to the scope of the regulatory processes announced on June 9, 2021.'' The agencies offer the following clarification. During the regional roundtables, the agencies anticipate discussing issues related to ''waters of the United States'' that will be applicable to the agencies' second rulemaking. The regional roundtables will serve as one part of a robust pre-proposal outreach and engagement strategy—including but not limited to consultation and engagement with state and tribal co-regulators—to gain an understanding of the scope of potential issues to address in the second rulemaking.

The October 25, 2021 **Federal Register** document also states: ''The agencies are inviting stakeholders to organize interested parties and regional participants that comprise up to 15 representatives for these roundtables.'' The agencies offer the following clarification. The agencies are requesting that stakeholders or organizations nominate an entire group of no more than 15 people (including the organizer) who represent diverse perspectives. Individuals should not nominate themselves alone to the agencies.

The document also states: ''Each nomination for a roundtable must include a proposed slate of participants representing perspectives of: Agriculture; conservation groups; developers; drinking water/wastewater management; environmental organizations; environmental justice communities; industry; and other key interests in that region.'' The agencies offer the following clarification. The agencies will consider nominations that lack representation from one or more of the named stakeholder groups. However, the agencies will give more weight in the selection process to those nominations that include stakeholders representing a more robust and wider range of perspectives.

The **Federal Register** document also stated: ''The agencies anticipate coordinating with elected officials that represent the location of selected roundtables.'' The agencies offer the following clarification. The agencies' intent is to coordinate with relevant states, tribes, and Alaska Native Villages regarding potential participation in selected roundtables.

The **Federal Register** document further stated: ''EPA cannot hold in-person public meetings at this time. The agencies will host these roundtables virtually. . . . The agencies also intend to livestream each roundtable to make them available for public viewing.'' The agencies offer the following clarification. Information on how to access the livestream will be posted on the agencies' websites once the roundtable dates/times have been established.

Additionally, the **Federal Register** document did not include information on roundtable agenda, format, or logistics. The agencies would like to clarify that roundtables will be run by a facilitator and will be scheduled for no more than two and a half hours in duration.

Additionally, the agencies will coordinate with roundtable organizers on further implementation planning once roundtables are selected.

Jaime A. Pinkham,

Acting Assistant Secretary of the Army (Civil Works), Department of the Army.

Radhika Fox,

Assistant Administrator, Environmental Protection Agency.

[FR Doc. 2021–24317 Filed 11–5–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 172

[Docket No. PHMSA–2021–0058 (HM–264A)]

RIN 2137–AF55

Hazardous Materials: Suspension of HMR Amendments Authorizing Transportation of Liquefied Natural Gas by Rail

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: PHMSA, in coordination with the Federal Railroad Administration (FRA), proposes to amend the Hazardous Materials Regulations to suspend authorization of liquefied natural gas (LNG) transportation in rail tank cars pursuant to a final rule published in July 2020, pending the earlier of either completion of a separate rulemaking under RIN 2137–AF54 evaluating potential modifications to requirements governing rail tank car transportation of LNG, or June 30, 2024.

DATES: Comments must be received by December 23, 2021. To the extent possible, PHMSA will consider late-filed comments as a final rule is developed.

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

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System; U.S. Department of Transportation, Docket Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: Include the agency name and docket number PHMSA–2021–0058 (HM–264A) or RIN 2137–AF55 for this rulemaking at the beginning of your comment. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. If sent by mail, comments must be submitted in duplicate. Persons wishing to receive confirmation of receipt of their comments must include a self-addressed stamped postcard.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or the DOT Docket Operations Office (*see* **ADDRESSES**).

Confidential Business Information: 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.'' Submissions containing CBI should be sent to Lily Ballengee, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary that PHMSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Lily Ballengee, Transportation Specialist, Standards and Rulemaking Division, Office of Hazardous Materials Safety, (202) 366–8553, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

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I. Overview

PHMSA, in coordination with FRA, proposes to suspend recent amendments to the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) authorizing transportation of ''Methane, refrigerated liquid,'' commonly known as LNG in DOT–113C120W9 specification rail tank cars while it conducts a thorough evaluation of the HMR's regulatory framework for rail transportation of LNG in a companion rulemaking under RIN 2137–AF54, and determines if any modifications are necessary. Transportation of LNG by rail tank car has not occurred and there is considerable uncertainty regarding whether any would occur in the time it takes for PHMSA to consider potential modifications to the existing, pertinent HMR requirements. However, PHMSA's proposed temporary suspension of the HMR provisions authorizing transportation of LNG in rail tank cars guarantees no such transportation will occur before its companion rulemaking has concluded or June 30, 2024, whichever is earlier, thereby: (1) Avoiding any risks to public health and safety or environmental consequences (to include direct and indirect greenhouse gas (GHG) emissions [1]) that are being evaluated in the companion rulemaking and in ongoing research efforts undertaken in collaboration with FRA and external technical experts; (2) assuring timely implementation of any mitigation measures and operational controls for rail tank car transportation of LNG identified in the companion rulemaking or those ongoing research efforts; (3) reducing the potential for economic burdens by ensuring that entities avoid ordering rail tank cars compliant with the current requirements when the companion rulemaking may adopt alternative requirements; and (4) enabling meaningful opportunity for consideration of the perspectives of diverse stakeholders.

PHMSA proposes to add a new special provision 439 that prohibits LNG transportation in rail tank cars until issuance of a final rule concluding the rulemaking proceeding under RIN 2137–AF54, or June 30, 2024, whichever is earlier. Therefore, if the temporary suspension is adopted in a final rule, the HMR will not authorize the transportation of LNG in rail tank cars until completion of the companion rulemaking or June 30, 2024, whichever is earlier. Rail transport of LNG may still be permitted on an *ad hoc* basis as authorized by the conditions of a PHMSA special permit (§ 107.105), or in a portable tank secured to a rail car pursuant to the conditions of an FRA approval (§ 174.63).

II. Background

A. LNG by Rail Final Rule

On May 7, 2018, PHMSA accepted a petition for rulemaking [2] from the Association of American Railroads (AAR) to allow the transportation of LNG by rail in DOT–113 tank cars and began drafting a notice of proposed rulemaking (NPRM) in consultation with FRA. On April 10, 2019, Executive Order 13868 (''Promoting Energy Infrastructure and Economic Growth'') [3] was published, which directed the Secretary of Transportation to propose regulations that ''treat LNG the same as other cryogenic liquids and permit LNG to be transported in approved rail tank cars'' and finalize that rulemaking within 13 months.[4] In October 2019, PHMSA issued the LNG by Rail NPRM, which proposed to amend the HMR to allow LNG to be transported in existing DOT–113 tank cars and sought comments (due within 60 days) on the potential need for additional operational controls.[5]

On December 5, 2019, PHMSA issued a DOT special permit (SP) 20534 to Energy Transport Solutions, LLC (ETS) to allow the transportation of LNG in existing DOT–113 tank cars from Wyalusing, PA, to Gibbstown, NJ, with no intermediate stops.[6] DOT–SP 20534 includes several safety control measures, including a requirement to conduct remote sensing for detecting and reporting internal pressure, location, and leakage, and a requirement to provide training to emergency response agencies that could be affected prior to the initial shipment of a tank car under the SP. ETS applied for the SP before the LNG by Rail NPRM was initiated. After issuing the SP, PHMSA re-opened the comment period on the proposed rule until January 13, 2020.[7]

On July 24, 2020, PHMSA published a final rule in the **Federal Register** revising the HMR to allow for the bulk transport of LNG in rail tank cars.[8] In the LNG by Rail final rule, the Final Environmental Assessment (FEA), and the Final Regulatory Impact Analysis (RIA), PHMSA evaluated the potential benefits of rail tank car transportation of LNG and weighed them against the potential public safety and environmental risks.[9] PHMSA coordinated with FRA to determine that those potential risks from rail tank car transportation of LNG would be at safe levels if such transportation were: (1) In DOT–113C120W specification rail tank cars—indicated by the new specification suffix ''9'' (DOT–113C120W9)—with

[1] PHMSA distinguishes between ''direct'' and ''indirect'' GHG emissions herein consistent with the meaning of those terms in pertinent Obama-Administration Council on Environmental Quality (CEQ) guidance. *See* CEQ, ''Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews'' at 16 & n. 42 (Aug. 1, 2016); CEQ, ''National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions'' 86 FR 10252 (Feb. 19, 2021) (encouraging agencies to use CEQ's 2016 guidance until CEQ issues an updated version of that guidance).

[2] Docket No. PHMSA–2017–0020–0002.

[3] 84 FR 15495 (Apr. 15, 2019).

[4] The Secretary has delegated such rulemaking duties to the PHMSA Administrator. *See* 49 CFR 1.97.

[5] 84 FR 56964 (Oct. 24, 2019).

[6] DOT–SP 20534 expires by its terms on November 30, 2021. However, ETS may request a renewal in accordance with § 107.109. *See https://cms7.phmsa.dot.gov/approvals-and-permits/hazmat/file-serve/offer/SP20534.pdf/2017088295/SP20534.*

[7] 84 FR 70491 (Dec. 23, 2019).

[8] 85 FR 44994 (Jul. 24, 2020) (LNG by Rail final rule).

[9] *See, e.g., id.* at 45024; FEA, Docket No. PHMSA–2018–0025–0478; RIA, Docket No. PHMSA–2018–0025–0479.

enhanced outer tank requirements; (2) subject to all applicable then-extant requirements of the HMR; and (3) subject to certain additional operational controls. The LNG by Rail final rule increased the thickness of DOT–113 outer tank shells from 7/16 to 9/16 inch (a 28.5 percent increase) and mandated use of stronger TC–128 Grade B normalized steel. With respect to this increase in tank shell thickness and strength, PHMSA noted that ''[w]hen divided by the large number of carloads that would be carried during a DOT–113's 50-year service life, the 9/16th inch TC–128B normalized steel outer tank is highly cost-effective in that it will mitigate the consequences of derailment involving LNG by reducing the number of tanks punctured in the unlikely event of an accident.'' [10] The LNG by Rail final rule also required operational controls for transportation of LNG by rail tank car, including routing analysis, improved train braking, and remote monitoring. PHMSA noted that the operational controls added in the final rule were expected to reduce the likelihood of an incident and reduce potential damages if an incident were to occur.[11] The LNG by Rail final rule went into effect on August 24, 2020.

On August 20, 2020, the Puyallup Tribe of Indians filed an administrative appeal of the LNG by Rail final rule, alleging, *inter alia,* that the rulemaking disproportionately exposed its members to environmental hazards (including those associated with climate change) and that PHMSA's engagement with the Tribe on the rulemaking was inadequate. PHMSA denied the Tribe's administrative appeal on November 13, 2020.[12]

B. Pending Petitions for Review of the LNG by Rail Final Rule

The LNG by Rail final rule is the subject of several petitions for judicial review. A group of 6 environmental groups, a coalition of attorneys general for 14 States and the District of Columbia, and the Puyallup Tribe of Indians filed separate petitions for review challenging PHMSA's LNG by Rail final rule. All of the petitioners ask the court to vacate the rule, alleging violations of the Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101–5127), the Administrative Procedure Act (APA; 5 U.S.C. 553 *et seq.*), and the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). The Puyallup Tribe also alleges violations of the Tribal consultation protocols under the National Historic Preservation Act (54 U.S.C. 300101 *et seq.*) and Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''),[13] as well as disparate impacts on the Tribe in violation of Executive Order 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') [14] and Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*).

The petitions have been consolidated within a single proceeding in the U.S. Court of Appeals for the D.C. Circuit. On March 16, 2021, the court granted PHMSA's unopposed motion to place the petitions in abeyance while PHMSA reviewed the LNG by Rail final rule pursuant to Executive Order 13990 (''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis'').[15]

C. PHMSA/FRA LNG Task Force

PHMSA established a joint LNG Task Force with FRA in January 2020 as part of its ongoing research efforts on the transportation of LNG. The LNG Task Force helped to identify areas of research that could inform potential future regulatory activity, as appropriate. To assist in identifying appropriate tasks within that effort, the LNG Task Force employed a risk-based framework directed toward:

- ''knowing the risk'' by improving DOT's knowledge of the types and extent of risk posed by LNG by rail transportation, with a focus on research and testing;
- ''predicting the risk'' by leveraging modeling and simulation software and tools to analyze LNG by rail operations and potential risk outcomes;
- ''reducing the risk'' by relating the possible strategies and technologies that decrease the risk of transporting LNG by rail tank cars, especially through track inspection and operational factors; and
- ''preparing for the risk'' by focusing on the emergency response community to ensure that—should an incident occur and the risks of LNG materialize—emergency responders have the awareness, training, and resources to keep themselves and the public safe.

The LNG Task Force ultimately identified and undertook 15 tasks to synthesize ongoing research and outreach activities. Those tasks are listed in Table 1 below.

TABLE 1—LNG TASK FORCE METHODOLOGY FOR ADDRESSING LNG BY RAIL RISK

Know the risk	Predict the risk	Reduce the risk	Prepare for the risk
• Empirical Review of International LNG Rail Transportation. • LNG Loading/Unloading Safety Evaluation. • Quantitative Risk Assessment of LNG Transportation. • Full-Scale Impact Testing on DOT–113 .. • LNG UN T75 Portable Tank Fire-Testing	• Evaluate Likely Number of Punctures and Derailment Simulation Models. • Develop Worst-Case Scenario Model .... • Safety/Security Route Risk Assessment • Train Energy and Dynamics Simulator (TEDS). • Modal Conversion Between LNG by Truck and Rail.	• Re-Evaluate Costs and Benefits of ECP Brakes. • Evaluation of Train Operational Controls. • Automated Track Inspection.	• Validate Emergency Responder Opinions and Needs. • Develop LNG Educational and Outreach Plan.

The LNG Task Force initially projected completion of the above tasks by late 2021. However, much of the LNG Task Force's work was interrupted by the coronavirus disease 2019 (COVID–19) public health emergency. Consequently, several tasks—including full-scale impact testing, puncture and derailment simulation modeling, and LNG portable tank pool fire testing—are not expected to be completed until sometime in 2022.

D. Transportation Research Board Study

Pursuant to the ''Further Consolidated Appropriations Act, 2020'' (Pub. L. 116–94), PHMSA and FRA partnered with the National Academy of Sciences, Engineering, and Medicine (NASEM) to conduct a study on the transportation of LNG in rail tank cars through a committee of the Transportation

[10] *Id.* at 45005.

[11] *Id.* at 45008.

[12] Docket No. PHMSA–2018–0025–0637.

[13] 65 FR 67249 (Nov. 9, 2000).

[14] 59 FR 7629 (Feb. 16, 1994).

[15] 86 FR 7037 (Jan. 25, 2021).

Research Board (TRB).[16] The TRB committee commenced work in mid-July 2020.

The TRB study consists of two phases, with each phase culminating in a report with findings and recommendations:

- Phase I reviews the plans and progress of the LNG Task Force to develop a report containing findings regarding the relevance, completeness, and quality of its efforts, and to offer recommendations for addressing any shortcomings.
- Phase II involves a more comprehensive assessment of topics relevant to the safe movement of LNG by rail tank car pursuant to both SP and the HMR. The Phase II Report will contain recommendations to Congress, PHMSA, FRA, industry, emergency responders, and other relevant stakeholders on necessary near- and long-term actions to improve understanding of the risks associated with transporting LNG by rail tank car, mitigate those risks, and prevent and prepare for potential incidents.

The TRB committee issued its Phase I Report on June 15, 2021.[17] Although the Phase I Report generally praised the LNG Task Force's ''comprehensive as planned'' program for making effective use of a ''number of long standing and high quality research and testing programs,'' the TRB committee noted that the COVID–19 public health emergency resulted in delays in initiation and completion of several tasks. The TRB committee also noted that the interdependency of many of those outstanding tasks complicated its and the LNG Task Force's work in developing a complete understanding of the risks associated with transportation of LNG in rail tank cars. It expressed particular concern regarding the incomplete status of tasks pertaining to full-scale impact testing, portable tank pool fire testing, worst-case scenario analysis, and quantitative risk assessment.[18] The TRB committee also emphasized pending tasks necessary to understand the potential risks to public and worker safety arising from releases during loading, unloading, and transloading of LNG tank cars, as well as in overcoming limited emergency planning and response training and resources.

The Phase I Report provided recommendations [19] for improving the assumptions, rationale, and methodology employed by the LNG Task Force in executing the outstanding tasks. The recommendations include that PHMSA and FRA should make several changes to the planned portable fire tank testing—including using LNG as the pool fire fuel and not liquefied petroleum gas—and assess the potential for cryogenic damage cascading to adjacent tanks. The report also recommends PHMSA and FRA enhance the modeling for worst-case scenarios—such as using a train speed of 50 miles-per-hour (mph) instead of 40 mph—and evaluate explosion hazards from a spill of LNG resulting in vapor dispersion in an environment with confined or congested spaces. Additionally, the report recommends PHMSA and FRA add loading and unloading operations and train assembly classification to the risk assessment for transport of LNG by rail as compared to highway.

The TRB committee plans to complete its work under Phase II in mid-2022.[20]

E. Executive Order 13990

Section 2(a) of Executive Order 13990 requires the review of agency regulations and other actions promulgated or adopted between January 20, 2017, and January 20, 2021, that are candidates for suspension, modification, or rescission because of inconsistency with Administration policies to improve public health, protect the environment, prioritize environmental justice, and reduce GHG emissions. The White House identified the LNG by Rail final rule in a non-exclusive list [21] of agency actions that would be reviewed in accordance with Executive Order 13990. Additionally, section 7 of Executive Order 13990 revokes Executive Order 13868, along with several other executive orders and executive actions, and directs agencies to promptly take steps, consistent with applicable law, to rescind any rules or regulations that had been issued ''implementing or enforcing'' those executive orders and executive actions.

On May 5, 2021, DOT issued a notice soliciting comment on potential candidates for review under Executive Order 13990 from among existing rules and other DOT actions.[22] DOT received one comment pertaining to the LNG by Rail final rule. In that comment, the Transportation Trades Department of the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) called for re-examination of the LNG by Rail final rule because it believes that rulemaking ''neglected to include meaningful safety measures to adequately address the inherent risks to this type of operation.'' [23]

III. Basis for Suspension

A. Development of a More Complete Understanding of the Risks and Benefits Associated With Rail Tank Car Transportation of LNG

The LNG by Rail rulemaking considered incorporating within the HMR regulatory requirements to protect the public, property, and the environment from unreasonable risks from transportation of LNG in rail tank cars. As such, PHMSA—in consultation with FRA—determined that existing HMR requirements including the modified DOT–113 tank car and new operational requirements prescribed in the LNG by Rail final rule, along with expected compliance with widely-accepted, voluntary industry standards such as AAR Circular OT–55 for shipments of LNG in rail tank cars, would reduce risk to safety, property, and the environment to acceptable levels in light of the potential benefits of that rulemaking.[24] That decision reflected consideration of LNG's hazardous properties and the safety record of the DOT–113 tank car.[25]

However, PHMSA acknowledged in the LNG by Rail final rule that additional further data and knowledge (for example regarding potential benefits as well as safety and environmental risks) could make appropriate further mitigations for shipping LNG by rail tank car.[26] The LNG by Rail final rule, RIA, and FEA were candid about uncertainty in the future market demand for transportation of LNG by rail tank car, potential direct and

[16] In that legislation, Congress earmarked funds for the NASEM study for the express purpose of ''inform[ing] rulemaking.'' NASEM maintains a website dedicated to the TRB committee's work that contains the TRB committee's charter, work product, meeting agendas, and other supporting material. *See* NASEM, ''Safe Transportation of Liquefied Natural Gas by Railroad Tank Car,'' *https://www.nationalacademies.org/our-work/safe-transportation-of-liquefied-natural-gas-by-railroad-tank-car (last visited Jun. 16, 2021).*

[17] NASEM, ''Preparing for LNG by Rail Tank Car: A Review of a U.S. DOT Safety Research, Testing, and Analysis Initiative'' (Jun. 2021) (Phase I Report), *https://www.nap.edu/read/26221/chapter/1.*

[18] *Id.* at 5–6.

[19] *Id.*

[20] *Id.* at 13.

[21] U.S. White House, ''Fact Sheet: List of Agency Actions for Review,'' *https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/* (last visited Jun. 16, 2021).

[22] 85 FR 23876.

[23] Docket No. DOT–OST–2021–0036–0025.

[24] *See, e.g.,* 85 FR 45003 (discussing reduction in risks from tank car enhancements, mandatory operational controls, and voluntary industry practices) *and* 45024 (discussing potential economic and other benefits from the LNG by Rail final rule).

[25] 85 FR 44998.

[26] *See, e.g.,* 85 FR 44995 (''PHMSA recognizes that there is ongoing and potential future research related to the transportation of LNG by all modes. The Agency will continue to use this research to inform potential future regulatory activity, as appropriate.'').

indirect GHG emissions associated with authorizing LNG by rail tank car, and the adequacy of emergency planning and response resources.[27] PHMSA sought to mitigate potential risks that were affected by those uncertainties by adopting certain requirements in the LNG by Rail final rule suggested by comments in the rulemaking docket.[28] PHMSA also stated that it may adjust the HMR's regulatory framework governing rail tank car transportation of LNG as more information became available from its oversight activities.[29] In fact, PHMSA had already begun work within the LNG Task Force on a comprehensive set of tasks directed toward refining PHMSA's knowledge of the risks of rail tank car transportation of LNG when it issued the LNG by Rail final rule. PHMSA also expected that it would have the benefit of the TRB committee's study on LNG by rail that Congress had directed for the express purpose of informing pertinent PHMSA rulemakings. Lastly, PHMSA understood it would have time to amend the HMR to integrate insights from those research activities, as it could take time to build a fleet of dedicated DOT–113C120W9 tank cars, as stated in the RIA.[30]

Uncertainty regarding the potential benefits and safety and environmental risks of rail transportation of LNG under the HMR has persisted longer than PHMSA anticipated when it issued the LNG by Rail final rule, and has in fact increased as a result of the release of the TRB Phase I Report on June 15, 2021. Uncertainty has persisted longer than expected because the COVID–19 public health emergency has delayed the completion of research efforts to confirm and enhance PHMSA and FRA's knowledge of public safety and environmental risks attendant in rail tank car transportation of LNG. As explained in the TRB Phase I Report, several of the tasks that had been scheduled for completion by early 2021 will not be completed before late 2021 or 2022. Delivery of the TRB Phase I Report was expected March 31, 2021, but the report was issued June 15, 2021.

Uncertainty also has increased because, while the TRB committee generally commended PHMSA and FRA's efforts under the LNG Task Force, the TRB committee identified a number of information gaps in its and the LNG Task Force's work that PHMSA was not aware of when it issued the LNG by Rail final rule. The gaps concern testing and the evaluation of public safety and environmental risks (*e.g.,* relating to full-scale impact testing, pool fire testing, worst-case analysis, and quantitative risk assessment)—including testing on which PHMSA had relied in the LNG by Rail final rule.[31] The data gaps identified by the TRB committee might have been resolved by this point in time, but they currently remain unresolved because of the disruptions caused by the COVID–19 public health emergency. Further, the committee identified opportunities to improve the work of the LNG Task Force in understanding the risks to the public, workers, and the environment from rail tank car transportation of LNG, which potentially could further reduce uncertainties in the future and put PHMSA in a better position to evaluate risks as it moves forward with its companion rulemaking. The TRB committee also emphasized the need for a robust understanding of the potential risks to public and worker safety arising from releases during loading, unloading, and transloading of LNG tank cars, and improved emergency planning and response training and resources, further underscoring the importance of PHMSA taking additional time to ensure it fully understands and considers uncertainties.

The COVID–19 public health emergency and other developments have also exacerbated uncertainties in near- and long-term market demand for rail transportation of LNG bounding the potential benefits and risks to public safety and the environment from the LNG by Rail final rule. The FEA supporting the LNG by Rail final rule acknowledged the complexity of the economics driving whether demand for natural gas transport outside the pipeline network as LNG would be met through the transportation in tank cars under the LNG by Rail final rule or by alternatives (one or more of highway transportation of LNG via MC–338 insulated cargo tanks, rail transportation of LNG pursuant to SP, or rail transportation of LNG via portable tank pursuant to FRA approval).[32] The COVID–19 public health emergency has complicated that calculus further by causing economic disruption throughout the natural gas industry, impacting LNG infrastructure investment directly.[33] Additionally, since the LNG by Rail final rule became effective, LNG markets have seen a number of announcements portending potentially fundamental supply and demand changes in international LNG markets.[34] Consequently, PHMSA believes there is more uncertainty now than when the LNG by Rail final rule was issued regarding whether, when, and where rail tank car transport of LNG—and by extension, any potential benefits and public safety/environmental risks—will materialize.

PHMSA believes the increased uncertainty regarding the potential benefits and safety and environmental consequences of rail transportation of LNG pursuant to the LNG by Rail final rule warrants temporary suspension while PHMSA evaluates (under RIN 2137–AF54) whether and under what circumstances the HMR should allow rail transportation of LNG. As explained above, research activity that PHMSA had expected would corroborate its understanding of the safety and environmental risks attendant in rail transportation of LNG has been delayed, while TRB's peer review of testing cited in the LNG by Rail final rule has raised additional questions.[35] Uncertainties in

[27] 85 FR 45016 (describing market demand uncertainties) and 45019–21 (describing ongoing efforts to improve emergency planning and emergency response training and resources); Docket No. PHMSA–2018–0025–0478 at 35 (discussing uncertainties regarding GHG emissions impacts of that rulemaking).

[28] 85 FR 44996.

[29] 85 FR 44995.

[30] Docket No. PHMSA–2018–0025-0479 at 19.

[31] *See* 85 FR 45006 (full-scale impact testing), 45012 (pool fire testing), and 45013 (quantitative risk assessment).

[32] Docket No. PHMSA–2018–0025–0478 at 11, 26–29.

[33] *See, e.g.,* Kravtosova & DiSavinio, Reuters, ''LNG Investments Vanish in 2020 as Coronavirus Slashes Oil and Gas Prices,'' (Sep. 9, 2020), *https://www.reuters.com/article/us-lng-exports-investment-analysis/lng-investments-vanish-in-2020-as-coronavirus-slashes-oil-and-gas-prices-idUSKBN2602PY.*

[34] *See, e.g.,* DiSavinio, Reuters, ''For LNG Developers, Another Year of Cancelled Projects'' (May 18, 2021), *https://www.reuters.com/business/energy/lng-developers-another-year-canceled-projects-2021-05-18/;* Shiryaevskaya, Stapczynski & Ratcliffe, Bloomberg, ''King of LNG Undercuts Rivals to Keep Dominating World Market'' (May 19, 2021), *https://www.bloomberg.com/news/articles/2021-05-19/king-of-lng-undercuts-rivals-in-bid-to-dominate-global-market;* Stapczynski. Bloomberg, ''Global LNG Market Faces Shakeup from Japan's Green Shift'' (Jul. 26, 2021), *https://www.bloomberg.com/news/articles/2021-07-26/japan-s-green-ambitions-threaten-the-lng-market-it-helped-create.*

[35] PHMSA also notes that, even as there is less certainty regarding the potential benefits associated with the LNG by Rail final rule, there is greater scientific certainty that one of those potential benefits would entail significant environmental consequences. Specifically, the LNG by Rail final rule touted the potential for increased natural gas (methane) production as a potential *benefit* of that rulemaking. *See, e.g.,* 85 FR 44995. However, more recent science has underscored the urgency of limiting such additional production for avoiding the worst consequences from anthropogenic climate change from indirect emissions associated with production and transportation activity. *See, e.g.,* ''Sixth Assessment Report—Working Group I: Physical Science Basis'' at TS–68, 6–11, 6–73 (Aug. 2021), *https://www.ipcc.ch/report/ar6/wg1/#FullReport* (last visited Aug. 19, 2021) (explaining the urgency of reducing GHG emissions—in

Continued

the underlying economic dynamics driving the potential benefits and public safety and environmental risks considered in the LNG by Rail final rule have increased (*e.g.,* the quantity of LNG that will move by rail, the routes involved, and whether new transportation capacity would induce more natural gas extraction). PHMSA believes these increased uncertainties cast doubt on the continued validity of the balance between potential benefits and public safety and environmental risks underpinning the LNG by Rail final rule.

A temporary suspension, however, will give PHMSA and FRA the opportunity to complete a comprehensive evaluation of the benefits and risks of rail tank car transportation of LNG in the companion rulemaking before any LNG moves by rail under the HMR. Although—as explained below—PHMSA and FRA understand that rail tank car transportation of LNG is neither occurring nor expected to occur in the near future, temporary suspension of the LNG by Rail final rule ensures avoidance of potential risks to public and worker safety and the environment from such transportation while that parallel rulemaking proceeds. Suspension would also ensure HMR authorization of rail transportation of LNG reflects the ''best science'' available,[36] including additional information obtained from the ongoing and delayed research efforts of the LNG Task Force, the forthcoming TRB Phase II Report expected in mid-2022, and continuing developments in scientific understanding of the near-term risks of climate change from enhanced natural gas transportation investments. Suspension would allow consideration of additional public comment, particularly on issues such as public and worker safety, environmental risks, and environmental justice, as well as on any additional testing or other information generated by PHMSA, FRA, and the TRB.

Therefore, PHMSA proposes to add a new special provision 439 prohibiting LNG transportation in rail tank cars until issuance of a final rule concluding the rulemaking proceeding under RIN 2137–AF54, or June 30, 2024, whichever is earlier.

B. No Material Adverse Impact on Reliance Interests

PHMSA does not expect temporary suspension of transporting LNG by rail tank car will have a material adverse impact on serious reliance interests. Despite issuance of the LNG by Rail final rule in July 2020, LNG has not been transported in rail tank cars, and PHMSA is unaware of any planned movements in the near future. The development of the necessary infrastructure—in particular, construction of DOT–113C120W9 tank cars—to transport LNG by rail under the HMR demands significant financial investment, long-term commitment, and considerable planning. The DOT–113C120W9 tank car was introduced for LNG transport and would be impractical for use with other hazardous materials because another, more feasible specification (*i.e.,* DOT–113C120W) is already available for other Class 2 cryogenic flammable liquids that are authorized to be transported by rail. Therefore, a dedicated LNG tank car fleet would need to be built, and there may be construction delays because of limited capacity in the rail car manufacturing industry. At this time, PHMSA is unaware of any orders having been placed for manufacture of new DOT–113C120W9 tank cars.

Nor are PHMSA and FRA aware of near-term plans to transport LNG in existing DOT–113 rail tank cards under DOT–SP 20534. ETS, the holder of DOT–SP 20534, is a subsidiary of New Fortress Energy Inc. (NFE) according to documents filed with the U.S. Securities and Exchange Commission (SEC). NFE develops and operates energy infrastructure, including LNG terminals, power generation facilities, and natural gas logistics infrastructure, and provides supply and logistics services to customers both domestically and internationally. NFE noted in its Q2–2021 Form 10–Q: Quarterly Report filed in August with the SEC that it has not yet issued a final notice to proceed to its engineering, procurement, and construction contractors for its liquefaction facility in Wyalusing, PA—an origination-point for the route authorized by PHMSA in DOT–SP 20534.[37] Further, noting the volatility of the current LNG market, NFE admits ''there can be no assurances that [it] will complete the Pennsylvania Facility or be able to supply [its] Facilities with LNG produced at [its] own Liquefaction Facilities.'' PHMSA also understands that NFE's Wyalusing, PA, facility is the subject of a pending, contested petition for Declaratory Order filed with the Federal Energy Regulatory Commission (FERC) that may determine whether that facility requires a FERC certificate before operating as an LNG export terminal.[38]

Nevertheless, while PHMSA does not expect the transport of LNG by rail tank car in the near future for the reasons discussed above, shippers may continue to seek authorization to transport LNG by rail in rail tank cars pursuant to a DOT SP issued by PHMSA or in portable tanks subject to an approval by FRA. PHMSA's SP procedures thoroughly explain the information applicants must include in their application and PHMSA's process, which includes public docketing, an opportunity for public comment, and an explanation for why an application is granted or denied.[39] The procedures also include an opportunity for reconsideration and an appeal process, after which a decision is the final administrative action.[40] FRA's approval process has similar procedures. Indeed, FRA recently received a petition from Alaska Railroad Corporation to extend an FRA approval to ship LNG by rail in portable tanks. In response to the requested extension, FRA published a notice of conditional approval and initiated a 60-day comment period ending on August 23, 2021, to ensure that FRA had opportunity to consider any additional views or information that stakeholders provided.[41] As PHMSA is unaware of any potential near-term movement of LNG by rail tank cars and any potential shippers could avail themselves of the SP (for the potential transportation of LNG by rail tank car) or FRA approval processes (for the potential transportation of LNG by portable tank on rail cars), PHMSA expects the proposed suspension of LNG by rail transportation to have a minimal economic impact. For more

particular, short-term contributors such as methane); Intl. Energy Agency, ''Net Zero by 2050: A Roadmap for the Global Energy Sector'' at 99 (May 2021) (noting the urgency of avoiding new natural gas production fields in order to meet net-zero policy goals).

[36] *See* ''Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking'' (Jan. 27, 2021), *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/ (requiring* Federal agencies to make ''evidence-based decisions'' informed by the ''best available science and data'' in their regulatory activity).

[37] New Fortress Energy Inc. 10–Q Quarterly Report for Quarter Ending June 30, 2021, (Aug. 6, 2021), *https://sec.report/Document/0001140361-21-027401/*. PHMSA also notes that ETS is required by ¶ 12 of DOT–SP 20534 to provide periodic reports on the status of efforts to manufacture and deliver tank cars intended for use pursuant to that SP.

[38] *See* FERC Docket No. CP20–524 (in re Petition for Declaratory Order of Bradford County Real Estate Partners LLC). Should FERC declare that an export facility certificate is needed, it could take an additional two years (or longer) to obtain that certificate from FERC.

[39] 49 CFR part 107, subpart B.

[40] 49 CFR part 107, subpart B.

[41] FRA, ''Notice of Conditional Approval,'' 86 FR 33472 (Jun. 24, 2021).

information, see discussion of the cost analysis in accordance with Executive Order 12866 (''Regulatory Planning and Review'').[42]

However, PHMSA solicits comment from stakeholders on potential economic, public safety, and environmental benefits and adverse impacts of the proposed rulemaking. PHMSA also solicits comments on the length of its proposed suspension period and whether PHMSA should modify its proposed expiration date. PHMSA notes that it selected the proposed date (June 30, 2024) for expiration of the temporary suspension to give PHMSA adequate time to incorporate the results of the forthcoming TRB Phase II Report—expected in mid-2022—within its companion rulemaking under RIN 2137–AF54.

IV. Regulatory Analyses and Notices

A. Statutory/Legal Authority

This NPRM is published under the authority of the Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101–5127). Section 5103(b) of the HMTA authorizes the Secretary of Transportation to ''prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce.'' The Secretary has delegated the authority granted in the HMTA to the PHMSA Administrator at 49 CFR 1.97(b).

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866 (''Regulatory Planning and Review'')[43] requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Agencies should consider quantifiable measures and qualitative measures of costs and benefits that are difficult to quantify. Further, Executive Order 12866 requires that ''agencies should select those [regulatory] approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.'' Similarly, DOT Order 2100.6A (''Rulemaking and Guidance Procedures'') requires that regulations issued by PHMSA and other DOT Operating Administrations should consider an assessment of the potential benefits, costs, and other important impacts of the proposed action and should quantify (to the extent practicable) the benefits, costs, and any significant distributional impacts, including any environmental impacts.

Executive Order 12866 and DOT Order 2100.6A require that PHMSA submit ''significant regulatory actions'' to the Office of Management and Budget (OMB) for review. This rulemaking is considered a significant regulatory action under section 3(f)(4) of Executive Order 12866 because the temporary suspension of the LNG by Rail final rule could raise novel legal or policy issues. This NPRM has, therefore, been reviewed by OMB.

As discussed at greater length above, PHMSA does not expect that the proposed temporary suspension of the amendments adopted in the LNG by Rail final rule will have material, adverse impacts. Should the proposed rule be adopted such that HMR authorization to move LNG by rail tank car is temporarily suspended, no LNG could move under the HMR in a rail tank car until PHMSA completes its companion rulemaking under RIN 2137–AF54, or June 30, 2024, whichever is earlier. Notwithstanding the considerable uncertainties regarding the market demand for rail tank car transportation of LNG, PHMSA expects little or no LNG transportation by rail tank car would have moved during the proposed suspension period for the reasons explained above; therefore, PHMSA expects little or no direct economic impact of a temporary suspension. Indeed, PHMSA's temporary suspension may in fact reduce economic burden by discouraging a shipper from ordering rail tank cars compliant with the LNG by Rail final rule when the companion rulemaking (under RIN 2137–AF54) may adopt different requirements. Additionally, should any potential shippers need to transport LNG by rail tank car during the suspension period, they could avail themselves of the PHMSA SP or FRA approval processes for such transport. Further, as explained below, temporary suspension guarantees avoidance of potential adverse public safety and environmental impacts (including, but not limited to, contribution of direct and indirect GHG emissions) that could have arisen from rail tank car transportation of LNG under the HMR. Lastly, PHMSA notes that the limited duration of its proposed suspension would also mitigate any adverse economic, public safety, or environmental impacts that could arise.

PHMSA acknowledges that, in the (unlikely) event demand for rail tank car transportation under the LNG by Rail final rule would materialize during the suspension period in the absence of this rule, the proposed temporary suspension could result in procedural or compliance costs, lost business opportunities, and safety and environmental risks. Obtaining and complying with the conditions imposed within PHMSA-issued DOT SPs and FRA approvals authorizing rail transportation of LNG would incur costs due to regulatory uncertainty, as well as delay and compliance burdens. Each of those consequences would entail higher procedural or compliance costs, which could in turn result in lost business opportunities, or at minimum, diminish the business benefits of rail transportation of LNG.[44] Further, the DOT SP and FRA approval alternatives would entail unique public safety and environmental risks, which are a function of the conditions imposed by each of PHMSA and FRA in each authorization.

Alternatively, the unavailability of HMR authorization for rail tank car transportation of LNG could prompt shipping LNG by highway via MC–338 insulated cargo tanks. This alternative may involve higher costs than rail transportation, as each MC–338 cargo tank (which has approximately half the capacity of a DOT–113 tank car) would have to be shipped individually, likely forfeiting the economies of scale from rail transportation via tank car (under the LNG by Rail final rule or a DOT SP) or ISO tank (under an FRA approval). For this reason, PHMSA does not expect shippers to opt for LNG transportation via MC–338 cargo tank as a substitute for rail tank car transportation pursuant to the LNG by Rail final rule. To the extent that transportation via MC–338 cargo tank does occur, it would entail different environmental risks (including, but not limited to, greater risk of accidents and more direct GHG emissions than rail transportation of the same volume of LNG) than the transportation of LNG by rail tank car.[45]

Therefore, PHMSA expects that, in the event that the proposed suspension of the LNG by Rail final rule has any adverse economic impact, it would consist largely of lost business opportunities as a result of higher procedural or compliance costs and lower economies of scale from

[42] 58 FR 51735 (Oct. 4, 1993).

[43] Ibid.

[44] *See, e.g.,* Docket No. PHMSA–2018–0025–00478 at 5, 30 (noting that the grantee of DOT–SP 20534 has indicated that it was unlikely to employ ISO tanks for rail transportation of LNG because of the high costs of that approach) *and* 35 (noting the potential for LNG by Rail final rule to create new business opportunities).

[45] *Id.* at 33–34, 56 (discussing higher direct GHG emissions from highway transportation) *and* 37–38 (discussing higher risk of crashes from highway transportation).

alternatives to rail transportation under the LNG by Rail final rule. Any such adverse economic impacts are expected to be unlikely and time-limited. Further, any lost business opportunities could be offset by avoided safety and environmental risks if the suspension reduces the transportation of LNG (*i.e.,* if it prevents transportation or production of LNG that would otherwise occur).

Because temporary suspension of the LNG by Rail final rule entails limited risk of adverse economic impact even as it guarantees avoidance of potential public safety and environmental impacts (including significant environmental risks such as indirect GHG emission contributions to climate change), PHMSA submits the proposed HMR amendments herein. PHMSA solicits comment from stakeholders on potential impacts of the proposed rulemaking.

C. Executive Order 13132

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism'')[46] and its implementing Presidential Memorandum (''Preemption'').[47] Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.''

This rulemaking may preempt State, local, and Native American Tribe requirements, but does not propose any regulation that has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

The Federal hazmat law contains an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) the packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) the preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) the design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This rule addresses subject items (2) and (5) above, which are covered subjects, and therefore, non-federal requirements that fail to meet the ''substantively the same'' standard are vulnerable to preemption under the Federal hazmat law. Moreover, PHMSA will continue to make preemption determinations applicable to specific non-federal requirements on a case-by-case basis, using the obstacle, dual compliance, and covered subjects tests provided in Federal hazmat law.

This rule also incorporates certain FRA requirements under the former Federal Railroad Safety Act of 1970, as repealed, revised, reenacted, and recodified (FRSA; 49 U.S.C. 20106), and the former Safety Appliance Acts, as repealed, revised, reenacted, and recodified (SAA; 49 U.S.C. 20301–20302, 20306) that may potentially preempt certain State requirements. Such FRSA and SAA requirements would apply to certain operators and offerors of LNG by Rail tank cars, including operational requirements for distributed power or two-way end-of-train (EOT) power braking systems.

D. Executive Order 13175

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13175 and DOT Order 5301.1 (''Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes''). Executive Order 13175 and DOT Order 5301.1 require DOT Operating Administrations to assure meaningful and timely input from Native American Tribal government representatives in the development of rules that significantly or uniquely affect tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the Federal government and Native American Tribes.

In addition to the petitions filed by the environmental groups and State attorneys general mentioned above, the Puyallup Tribe also challenged the LNG by Rail final rule and alleged violations of the Tribal consultation protocols under the National Historic Preservation Act and Executive Order 13175 and disparate impacts on the Tribe in violation of Executive Order 12898 and Title VI of the Civil Rights Act of 1964.

PHMSA assessed the impact of this rulemaking and expects that it will not significantly or uniquely affect Tribal communities or Native American Tribal governments. This rulemaking does not impose substantial compliance costs on Native American Tribal governments, nor does it mandate Tribal action. Insofar as PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect it would entail disproportionately high adverse risks for Tribal communities. PHMSA submits that the proposed rulemaking could in fact reduce risks to Tribal communities, as it could avoid the release of hazardous materials by railroad in the vicinity of Tribal communities. For these reasons, PHMSA does not expect the funding and consultation requirements of Executive Order 13175 and DOT Order 5301.1 to apply. However, PHMSA solicits comment from Native American Tribal governments and communities on potential impacts of the proposed rulemaking.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider whether a rulemaking would have a ''significant economic impact on a substantial number of small entities'' to include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'')[48] requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to ''thoroughly review draft rules to assess and take appropriate account of the potential impact'' of the rules on small businesses, governmental jurisdictions,

[46] 64 FR 43255 (Aug. 10, 1999).

[47] 74 FR 24693 (May 22, 2009).

[48] 67 FR 53461 (Aug. 16, 2002).

and small organizations. The DOT posts its implementing guidance on a dedicated web page.[49]

This rulemaking has been developed in accordance with Executive Order 13272 and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered. As explained above, PHMSA expects that the temporary suspension of the LNG by Rail final rule proposed herein will not have a significant economic impact generally, much less a significant economic impact on a substantial number of small entities. However, PHMSA solicits comments on the anticipated economic impacts to small entities.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), no person is required to respond to any information collection unless it has been approved by OMB and displays a valid OMB control number. Pursuant to 44 U.S.C. 3506(c)(2)(B) and 5 CFR 1320.8(d), PHMSA must provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests.

PHMSA has analyzed this NPRM in accordance with the Paperwork Reduction Act. PHMSA currently accounts for security plan burdens under OMB Control Number 2137–0612, ''Hazardous Materials Security Plans.'' In the LNG by Rail final rule, PHMSA required any rail carrier transporting a tank car quantity of UN1972 (Methane, refrigerated liquid (cryogenic liquid) or Natural gas, refrigerated liquid (cryogenic liquid)) to comply with the additional rail transportation safety and security planning requirements. Following publication of the LNG by Rail final rule, PHMSA published both a 60-day [50] and 30-day [51] notice and comment to provide an opportunity for public comment on the estimated increase in burden. PHMSA did not receive comments to either notice. Subsequently, PHMSA submitted the revision to OMB and received approval for the increased burden. As PHMSA proposes a temporary suspension of the authorization to ship LNG by rail tank car, as was codified in the LNG by Rail final rule, PHMSA estimates this rulemaking would result in a decrease in the burden associated with additional rail transportation safety and security planning requirements. The following reflects this estimated decrease in burden:

Decrease in primary route analysis	Change in number of railroads	Decrease in number of routes	Burden hours per route	Decrease in total burden hours	Salary cost per hour [52]	Decrease in total salary cost	Decrease in total burden cost
Class I Railroads	0	(2)	80	(160)	$73.98	($11,837)	$0
Class II Railroads	0	(1)	80	(80)	73.98	(5,919)	0
Class III Railroads	0	(1)	40	(40)	73.98	(2,959)	0
Total	0	(4)		(280)		(20,715)	0

Decrease in alternate route analysis	Change in number of railroads	Decrease in number of routes	Burden hours per route	Decrease in total burden hours	Salary cost per hour [53]	Decrease in total salary cost	Decrease in total burden cost
Class I Railroads	0	(2)	120	(240)	$73.98	($17,756)	$0
Class II Railroads	0	(1)	120	(120)	73.98	(8,878)	0
Class III Railroads	0	(1)	40	(40)	73.98	(2,959)	0
Total	0	(4)		(280)		(29,593)	0

Total AnnualDecrease in Number of Respondents: 0.

Total Annual Decrease in Number of Response: 8.

Total Annual Decrease in Burden Hours: 680.

Total Annual Decrease in Salary Costs: $50,308.

Total Annual Decrease in Burden Costs: $0.

PHMSA requests comments on the information collection and recordkeeping burden that would be reduced by the temporary suspension of the LNG by Rail final rule. Address written comments to the DOT Docket Operations Office as identified in the **ADDRESSES** section of this rulemaking. Comments regarding information collection burdens must be received prior to the close of the comment period identified in the **DATES** section of this rulemaking. Requests for a copy of this information collection should be directed to Steven Andrews or Shelby Geller, (202) 366–8553, *ohmspra@dot.gov,* Standards and Rulemaking Division (PHH–10), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. If these proposed HMR amendments are adopted in a final rule, PHMSA will submit the revised information collection and recordkeeping requirements to OMB for approval.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any NPRM or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, or by the private sector of $100 million or more in 1996 dollars in any given year,

[49] DOT, ''Rulemaking Requirements Related to Small Entities,'' *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities* (last visited Jun. 17, 2021).

[50] 85 FR 46220 (Jul. 31, 2020).

[51] 85 FR 73128 (Nov. 16, 2020).

[52] Occupation labor rates based on 2020 Occupational and Employment Statistics Survey (OES) for ''Transportation, Storage, and Distribution Managers (11–3071)'' in the Transportation and Warehousing industry. *See https://www.bls.gov/oes/current/oes113071.htm.* The hourly mean wage for this occupation ($50.53) is adjusted to reflect the total costs of employee compensation based on the BLS Employer Costs for Employee Compensation Summary, which indicates that wages for civilian workers are 68.3 percent of total compensation (total wage = wage rate/wage % of total compensation).

[53] Ibid.

the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This proposed rulemaking does not impose unfunded mandates under the UMRA. As explained above, it is not expected to result in costs of $100 million or more in 1996 dollars on either State, local, or Tribal governments, in the aggregate, or to the private sector in any one year, and is the least burdensome alternative that achieves the objective of the rule.

H. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*), requires that Federal agencies analyze proposed actions to determine whether the action will have a significant impact on the human environment. CEQ implementing regulations (40 CFR parts 1500–1508) require Federal agencies to conduct an environmental review considering (1) the need for the action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process. DOT Order 5610.1C (''Procedures for Considering Environmental Impacts'') establishes DOT procedures for evaluation of environmental impacts under NEPA and its implementing regulations.

(1) The Need for the Action

PHMSA has determined that the recommendations from the TRB committee, its ongoing research, and recent events stemming from the COVID–19 public health emergency predicate the need to re-evaluate the amendments authorized in the LNG by Rail final rule. Research activity that PHMSA had expected would enhance its understanding of the risks attendant in rail transportation of LNG has been delayed, and uncertainties have increased in whether there will be any potential benefits, and in the underlying economic dynamics bounding those risks (*e.g.,* the quantity of LNG that will move by rail, and the routes involved). Therefore, PHMSA proposes to amend the HMR to suspend authorization of LNG transportation in a rail tank car pending further analysis and completion of a companion rulemaking that will consider changes to the conditions under which LNG could be moved by rail, to potentially include additional safety, environmental, and environmental justice protections. This action will provide PHMSA an opportunity to review recent actions that could be obstacles to Administration policies promoting public health and safety, the environment, and climate change mitigation; and to evaluate the results of ongoing and delayed research efforts to ensure the safe transportation of LNG by rail tank car.

(2) Alternatives to the Action

In proposing this rulemaking, PHMSA is considering the following alternatives:

No Action Alternative

If PHMSA were to select the No Action Alternative, current regulations authorizing the transport of LNG in rail tank cars would remain in effect and no provisions would be amended or added. Therefore, the HMR would continue to authorize the transportation of LNG in DOT–113C120W9 tank cars with a 9/16-inch outer tank composed of TC–128B normalized steel. The following operational controls and safety measures would also remain in effect:

- Each tank car must be operated in accordance with § 173.319, which includes:
  - Testing of relief valves every 5 years
  - annual replacement of rupture discs
  - thermal integrity tests following an average daily pressure rise during any shipment exceeding 3 psig per day
  - other requirements specific to liquids in cryogenic tank cars.
- 49 CFR part 179, subpart F contains detailed design, construction, and operational requirements for DOT–113C120W tank cars with the specification suffix ''9'' to be used in rail transportation of LNG.
- Trains transporting 20 or more tank cars of LNG in a block, or 35 such tank cars throughout the train, must be equipped and operated with a two-way EOT device, pursuant to the requirements in 49 CFR part 232, subpart E, or a distributed-power (DP) locomotive as defined in 49 CFR 229.5.
- The offeror must remotely monitor each tank car while in transportation for pressure and location.
- The offeror must notify the carrier if the tank pressure rise exceeds 3 psig over any 24-hour period.
- Trains transporting any quantity of LNG must comply with the route planning requirements in § 172.820, which requires rail carriers transporting LNG by rail tank car to conduct an annual route analysis considering, at a minimum, 27 risk factors listed in appendix D to part 172.
- Each LNG tank car must have:
  - A reclosing pressure relief device with a start-to-discharge pressure of 75 psig;
  - a non-reclosing pressure relief device set to discharge at the tank test pressure;
  - a maximum permitted filling density (percent by weight) of 37.3 percent;
  - a design service temperature of −162 °C (−260 °F);
  - a maximum pressure when offered for transportation not to exceed 15 psig;
  - a minimum steel thickness, after forming, on the outer tank shell and tank heads of 9/16 inch, which is thicker than the requirement for other DOT–113C120W tank cars; and
  - an outer tank shell constructed of AAR TC–128, Grade B normalized steel plate as specified in § 179.100–7(a), which has a higher tensile strength of 81,000 psi which makes it stronger than that used for the existing DOT–113 outer shell.

The FEA, which—except for the finding of no significant impact therein—is adopted by reference into this NPRM, examined how the above requirements were imposed to reduce risks to human safety and the environment from the transportation of LNG in rail tank cars and incidents occurring as a result of this transportation.[54] The No Action Alternative would allow the shipment of LNG in rail tank cars, and PHMSA could continue to consider whether additional mitigations are necessary based on the expert recommendations from the TRB Phase I Report and results from ongoing and delayed research efforts.

Proposed Action Alternative

This alternative is the current proposal as it appears in this NPRM, proposing to add a new special provision to the HMR that would suspend the transportation of LNG in rail tank cars while PHMSA undergoes a comprehensive review to ensure the safe transportation of LNG by rail in accordance with ongoing research and incorporation of recommendations from the TRB, as well as the best available economic analysis and climate science. Rail transport of LNG would be permitted only on an *ad hoc* basis as authorized by the conditions of a PHMSA special permit (49 CFR 107.105) or in a portable tank secured to a rail car pursuant to the conditions of an FRA approval (49 CFR 174.63). The proposed amendments included in this alternative are more fully discussed in

[54] *See* Docket No. PHMSA–2018–0025–0478.

the preamble and regulatory text sections of this NPRM.

(3) Probable Environmental Impacts of the Action and Alternatives

No Action Alternative

If PHMSA were to select the No Action Alternative, current regulations would remain in place without suspension. As described in the FEA, the No Action Alternative could pose risks to public safety and the environment because the authorization under the HMR to offer shipments of LNG by rail tank car would remain in place. LNG poses potential hazards as a cryogenic liquefied flammable gas, including cryogenic temperature exposure, fire, and asphyxiation hazards. Transportation of any hazardous material introduces risk to safety and the environment, and each additional tank car theoretically increases the overall risk of an incident occurring and the quantity that could be released in the event of a derailment. While this is true for all hazardous materials transportation, PHMSA seeks to better understand the risks inherent to LNG transportation in the DOT–113C120W9, especially given the LNG by Rail final rule authorized large quantities to be transported at some point in the future. The 2020 FEA explained that transporting LNG in rail tank cars is expected to be safer than transporting LNG by truck on highways—however, it is possible that allowing LNG to be transported in rail tank cars would increase the amount of LNG transported, and therefore a direct comparison of the risks by rail and highway may be misleading. PHMSA will also consider, based on existing rail infrastructure locations and anticipated routes, whether transportation of LNG in rail tank cars could pose disproportionate harm or risk to communities of color or low-income communities. As described in the preamble to this proposed rule, various market and other uncertainties exist regarding specific routes that may be used for the transport of LNG by rail tank car.

No release of LNG vapor to the environment is allowed during the normal transportation of LNG in tank cars whether by roadway or railway. However, methane is odorless, and LNG contains no odorant, making detection of a release resulting from an incident difficult without a detection device. Releases of LNG due to venting or to accidents, without immediate ignition, involving either an MC–338 cargo tank, a portable tank, or a DOT–113C120W9 rail tank car have the potential to create flammable vapor clouds of natural gas because recently gasified LNG does not dissipate in the atmosphere as quickly as ambient-temperature natural gas. Large releases of LNG due to the breach of the inner tank of these transport vessels could result in a pool fire, vapor fire, and explosion hazards if methane vapors become confined. These flammability hazards pose a risk of higher potential impacts than localized cryogenic hazards.

Some commenters to the LNG by Rail final rule argued that the authorization of LNG by rail would further incentivize the production of natural gas, which is a fossil fuel. Methane has much greater heat trapping potential in the atmosphere than carbon dioxide in the short term. Thus, methane is considered a potent GHG, and comprises a significant portion of the United States' GHG emissions. While methane leaks are highly unlikely during transportation in the DOT–113C120W9 due to tank car design, increased natural gas production could lead to indirect environmental impacts of increased methane emissions released during production, loading and unloading, or at other times during its life cycle. In considering whether the authorization could further incentivize the production of natural gas, PHMSA will consider the scope of existing natural gas production and transportation via natural gas pipeline and other modes of transportation.

The FEA for the LNG by Rail final rule discussed potential environmental benefits that could be associated with the authorization to transport LNG by rail tank car. First, PHMSA discussed that the authorization could allow for the delivery of natural gas to locations dependent on more polluting energy forms, such as coal, diesel, heating oil, or firewood.[55] Use of natural gas in such areas, whether foreign or domestic, could allow for a reduction in polluting and climate-warming emissions. Additionally, the authorization to transport LNG by rail tank car could potentially replace some shipments of LNG by highway. As discussed in the FEA for the LNG by Rail rule, highway transportation is less efficient in comparison to rail transportation when considering fuel use, combustion emissions, and climate change impacts. However, in order to supplement, reduce, or replace highway transportation, rail infrastructure would need to exist between the origin and destination locations or be developed. Finally, the FEA explored industry claims that the authorization could incentivize the capture, storage, and liquefaction of natural gas over venting and flaring of natural gas during oil production and other industrial activities, in areas where natural gas pipeline capacity is unavailable. Facilitating the productive end use of by-product methane could reduce the venting and flaring of natural gas, which causes methane and carbon dioxide emissions. Similar to other above-described benefits, it is difficult to predict the extent to which industries would invest in the equipment, technology, and expertise necessary to pursue natural gas capture, storage, and liquefaction necessary to pursue LNG transportation by rail. A suspension of the authorization to transport LNG by rail could curtail these potential benefits in the near term.

Proposed Action Alternative

Under the Proposed Action Alternative, PHMSA would amend the HMR to suspend authorization of LNG transportation in rail tank cars pending further analysis and completion of a companion rulemaking or June 30, 2024, whichever is earlier. Therefore, the HMR would not authorize shippers to transport bulk quantities of LNG by rail tank car. Instead, LNG by rail would only be permitted pursuant to a DOT SP or in portable tanks subject to FRA approval. The Proposed Action Alternative would avoid the risks that transportation of LNG in rail tank cars, and particularly potential derailments of rail cars transporting LNG, could pose to public safety and the environment. PHMSA would be able to further consider whether the transportation of LNG could pose disproportionate harm or risk to communities of color and communities with low incomes, which have historically borne the brunt of deleterious Federal policy decisions. PHMSA would also be able to further consider whether shipping LNG in rail tank cars is consistent with public health and safety, environmental protection, and climate change mitigation; and to evaluate the results of ongoing and delayed research efforts and collaboration as part of an accompanying rulemaking under RIN 2137–AF54.

[55] *See, e.g.,* EPA, Press Release, ''State of Alaska and Fairbanks North Star Borough receive $14.7 Million EPA grant to improve air quality,'' (Nov. 2020), *https://www.epa.gov/newsreleases/state-alaska-and-fairbanks-north-star-borough-receive-147-million-epa-grant-improve-air* (''The Borough will use the grant funds to continue a woodstove changeout and conversion program focused on converting more wood burning appliances to cleaner burning liquid or gas-fueled heating appliances, which have a very low output of particulate pollution and higher fuel efficiency. Wood smoke contributes up to 60 to 80 percent of fine particle pollution levels measured in the Fairbanks North Star Borough.'').

However, as noted in the FEA for the LNG by Rail final rule, the use of MC–338 cargo tanks and portable tanks for LNG could increase over time if rail transport in tank cars were not authorized. Thus, shippers could have to rely on less efficient transportation mechanisms in the interim, as highway transportation requires more vehicles to move the same amount of material as rail transportation—if this occurs, the potential environmental benefits that could result from the transportation of bulk quantities of LNG by rail car discussed above would not be realized in the short term. However, as explained above, PHMSA does not expect that significant quantities of LNG would be shipped in rail tank cars during the suspension period. Further, the loss of economies of scale associated with transport of LNG by rail tank car could inhibit switching to MC–338 cargo tanks.

(4) Agencies and Persons Consulted During the Consideration Process

PHMSA has coordinated with FRA, the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, and the U.S. Coast Guard in the development of this proposed rule. The NPRM has also been made available to other Federal agencies within the interagency review process contemplated under Executive Order 12866. PHMSA solicits, and will consider, comments on the NPRM's potential impacts on safety and the environment submitted by members of the public, State and local governments, Tribal communities, and industry.

(5) Proposed Finding of No Significant Impact

The adoption of the Proposed Action Alternative's proposed suspension would prohibit the transportation of LNG in rail tank cars while PHMSA and FRA undertake a comprehensive analysis of safety and environmental issues associated with the transportation of LNG by rail. As such, PHMSA expects that the HMR amendments in the NPRM would have no significant impact on the human environment. PHMSA expects that the Proposed Action Alternative would allow PHMSA to review new information to evaluate the potential impact on safety, environmental justice, and GHG emissions. Further, based on PHMSA's analysis of these provisions described above and insofar as there has been no significant progress toward the movement of LNG by rail tank car, PHMSA proposes to find that codification and implementation of the proposed rule would not result in a significant impact to the human environment.

PHMSA welcomes any views, data, or information related to environmental impacts that may result from NPRM's proposed requirements, the No Action Alternative, and other viable alternatives and their environmental impacts.

I. Executive Order 12898

Executive Orders 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations''),[56] 13985 (''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government''),[57] 13990 (''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis''),[58] 14008 (''Tackling the Climate Crisis at Home and Abroad''),[59] and DOT Order 5610.2C (''Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects of their programs, policies, and activities on minority populations, low-income populations, and other underserved and disadvantaged communities.

PHMSA has evaluated this proposed rule under the above Executive Orders and DOT Order 5610.2C, and expects it would not cause disproportionately high and adverse human health and environmental effects on minority, low-income, underserved, and other disadvantaged populations and communities. The rulemaking is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. And insofar as PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect the proposed revisions would entail disproportionately high adverse risks for minority populations, low-income populations, or other underserved and disadvantaged communities.

The proposed rulemaking could reduce risks to minority populations, low-income populations, or other underserved and disadvantaged communities. Insofar as the proposed HMR amendments could avoid the release of hazardous materials, the proposed rule could reduce risks to populations and communities—including any minority, low-income, underserved, and disadvantaged populations and communities—in the vicinity of railroad lines. However, as noted in the FEA for the LNG by Rail final rule, access to LNG may result in potential economic benefits for underserved communities because of the efficiencies of transporting LNG by rail, and thereby domestic production, distribution, and consumption of natural gas could increase. These potential economic benefits that could result from the transportation of bulk quantities of LNG by rail car would not be realized by underserved communities in the short term. In addition, to the extent that suspending shipment of LNG by rail tank car could increase demand for shipping LNG by truck on highways, the proposed HMR amendments could increase risks to environmental justice communities in the vicinity of those highways.

PHMSA solicits comment on potential impacts to minority, low-income, underserved, and other disadvantaged populations and communities of the proposed rulemaking.

J. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000,[60] or on DOT's website at *http://www.dot.gov/privacy.*

K. Executive Order 13609 and International Trade Analysis

Executive Order 13609 (''Promoting International Regulatory Cooperation'')[61] requires that agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete

[56] 59 FR 7629 (Feb. 16, 1994).
[57] 86 FR 7009 (Jan. 25, 2021).
[58] 86 FR 7037 (Jan. 25, 2021).
[59] 86 FR 7619 (Feb. 1, 2021).
[60] 65 FR 19475 (Apr. 11, 2000).
[61] 77 FR 26413 (May 4, 2012).

internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards in order to protect the safety of the American public. PHMSA has assessed the effects of this rulemaking to ensure that it does not cause unnecessary obstacles to foreign trade. While the proposal to suspend the transport of LNG by rail tank car has potential to impact the United States' export of bulk LNG internationally, there has been no significant reliance interest or progress toward the near-term movement of LNG by rail tank cars. As such, PHMSA expects the amendments herein to pose a minimal impact to international trade if adopted. Therefore, PHMSA proposes to amend the HMR to suspend authorization of LNG transportation in a rail tank car pending further analysis to ensure potential future regulatory actions to allow bulk transport of LNG by rail promote public health and safety, the environment, and climate change mitigation. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

L. Executive Order 13211

Executive Order 13211 (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'')[62] requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' Executive Order 13211 defines a ''significant energy action'' as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy (including a shortfall in supply, price increases, and increased use of foreign supplies); or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs (OIRA) as a significant energy action.

Although this proposed rule is a significant action under Executive Order 12866, PHMSA expects it to have an annual effect on the economy of less than $100 million. Further, this action is not likely to have a significant adverse effect on the supply, distribution, or use of energy in the United States. While the proposal to suspend the transport of LNG by rail tank car has potential to impact the supply, distribution, or use of energy in the United States, PHMSA does not anticipate any near-term movement of LNG by rail tank cars. For additional discussion of the anticipated economic impact of this rulemaking, please see discussion of the cost analysis in accordance with Executive Order 12866 (''Regulatory Planning and Review'').

[62] 66 FR 28355 (May 22, 2001).

List of Subjects in 49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Incorporation by reference, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA proposes to amend 49 CFR part 172 as follows:

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 2. In § 172.101, amend the Hazardous Materials Table by revising the entry for ''Methane, refrigerated liquid *(cryogenic liquid) or* Natural gas, refrigerated liquid *(cryogenic liquid), with high methane content)*'' to read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

§ 172.101—HAZARDOUS MATERIALS TABLE

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification numbers	PG	Label codes	Special provisions (§ 172.102)	(8) Packaging (§ 173.***)			(9) Quantity limitations (*see* §§ 173.27 and 175.75)		(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
		*	*	*		*	*		*	*			
	Methane, refrigerated liquid *(cryogenic liquid) or* Natural gas, refrigerated liquid *(cryogenic liquid, with high methane content).*	2.1	UN1972		2.1	T75, TP5, 439, 440.	None	None	318, 319	Forbidden	Forbidden	D	40
		*	*	*		*	*		*	*			

* * * * *

■ 3. In § 172.102, revise paragraph (c)(1) by adding special provision 439 in numerical order to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

439 UN1972 is not authorized for transportation by rail tank car until issuance of either a final rule concluding the rulemaking action proceeding under RIN 2137–AF54, or June 30, 2024, whichever occurs first. For information and the status of RIN 2137–AF54, please refer to the Office of Management and Budget's Office of Information and Regulatory Affairs at *www.reginfo.gov.*

* * * * *

Issued in Washington, DC, on October 19, 2021, under authority delegated in 49 CFR 1.97.

William S. Schoonover,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2021–23132 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2021–0053; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BF38

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Miami Tiger Beetle

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; extension of comment period, and announcement of public hearing.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are extending the public comment period on our September 7, 2021, proposed rule to designate critical habitat for the Miami tiger beetle (*Cicindelidia floridana*) under the Endangered Species Act of 1973 (Act), as amended. We are taking this action to conduct a public hearing and to allow all interested parties additional time to comment. Comments previously submitted need not be resubmitted and will be fully considered in preparation of the final rule.

DATES: *Comment submission:* The comment period for the proposed rule published on September 7, 2021 (86 FR 49945), is extended. We will accept comments received or postmarked on or before December 23, 2021. Please note that comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date, and comments submitted by U.S. mail must be postmarked by that date to ensure consideration.

Public hearing: On December 2, 2021, we will hold a public hearing from 6 to 7:30 p.m., Eastern Time, using the Zoom platform (for more information, see *Public Hearing,* below).

ADDRESSES: *Availability of documents:* You may obtain copies of the September 7, 2021, proposed rule and associated documents on the internet at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2021–0053.

Comment submission: You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter the RIN or docket number, which are displayed in the initial headings of this document. For best results, do not copy and paste the RIN or docket number; instead, type the RIN or docket number into the Search box using hyphens. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.'' Please ensure you have located the correct document before submitting your comments.

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R4–ES–2021–0053, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

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

FOR FURTHER INFORMATION CONTACT: Lourdes Mena, Division Manager, Florida Classification and Recovery, U.S. Fish and Wildlife Service, Florida Ecological Services Field Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256–7517; telephone 904–731–3134. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

On September 7, 2021, we published a proposed rule (86 FR 49945) to designate critical habitat for the Miami tiger beetle under the Act. The proposed rule established a 60-day public comment period, ending November 8, 2021. During the comment period, we received a request for a public hearing. Therefore, we are announcing a public hearing and a 45-day extension of the September 7, 2021, proposed rule's comment period (see **DATES**, above) to allow the public an additional opportunity to provide comments on the proposed rule.

For a description of previous Federal actions concerning the Miami tiger beetle and information on the types of comments that would be helpful to us in promulgating this rulemaking action, please refer to the September 7, 2021, proposed rule (86 FR 49945).

Public Hearing

We are holding a public hearing to accept comments on the proposed rule on the date and at the time listed in **DATES**. We are holding the public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. All participants must register in order to listen and view the hearing via Zoom, listen to the hearing by telephone, or provide oral public comments at the hearing by Zoom or telephone. For information on how to register, or if technical problems occur joining Zoom on the day of the hearing, visit *https://www.fws.gov/southeast/florida.* Registrants will receive the Zoom link and the telephone number for the public hearing. If applicable, interested members of the public not familiar with the Zoom platform should view the Zoom video tutorials (*https://support.zoom.us/hc/en-us/articles/206618765-Zoom-video-tutorials*) prior to the public hearing.

The public hearing will provide interested parties an opportunity to present verbal testimony (formal, oral comments) regarding the September 7, 2021, proposed rule to designate critical habitat for the Miami tiger beetle (86 FR 49945). The public hearing will not be an opportunity for dialogue with the Service, but rather a forum for accepting formal verbal testimony. In the event there is a large attendance, the time allotted for oral statements may be limited. Therefore, anyone wishing to make an oral statement at the public

hearing for the record is encouraged to provide a prepared written copy of their statement to us through the Federal eRulemaking Portal, or U.S. mail (see **ADDRESSES**, above). There are no limits on the length of written comments submitted to us. Anyone wishing to make an oral statement at the public hearing must register before the hearing (*https://www.fws.gov/southeast/florida*). The use of a virtual public hearing is consistent with our regulations at 50 CFR 424.16(c)(3).

Reasonable Accommodation

The Service is committed to providing access to the public hearing for all participants. Closed captioning will be available during the public hearing. Participants will also have access to live audio during the public hearing via their telephone or computer speakers. Persons with disabilities requiring reasonable accommodations to participate in the hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the date of the hearing to help ensure availability. An accessible version of the Service's presentation will also be posted online at *https://www.fws.gov/southeast/florida* prior to the hearing (see **DATES**, above). See *https://www.fws.gov/southeast/florida* for more information about reasonable accommodation.

Public Comments

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via hard copy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.* Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Authors

The primary authors of this document are staff members of the Florida Ecological Services Field Office and Interior Regions 2/4 Regional Office.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–24357 Filed 11–5–21; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 86, No. 213
Monday, November 8, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary (OSEC), Department of Agriculture.

ACTION: Notice of new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular No. A–108, notice is hereby given that the Office of the Secretary (OSEC), a component within the United States Department of Agriculture (USDA or ''the Department''), proposes to develop a new system of records notice titled, ''USDA Personnel Public Health Emergency Records System.'' USDA/OSEC–01 proposes to establish this system of records to protect the Department's workforce and respond to Coronavirus Disease 2019 (COVID–19), a declared public health emergency, and other high-consequence public health threats.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is effective upon publication, subject to a 30-day period in which to comment on the routine uses, described below.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments by mail to the United States Department of Agriculture, Privacy Office, ATTN: Privacy Analyst, 1400 Independence Ave. SW, Washington, DC 20250; by telephone at 202–384–5026; or by email at *SM.OCIO.CIO.UsdaPrivacy.*

FOR FURTHER INFORMATION CONTACT: Sullie Coleman, Chief Privacy Officer, 1400 Independence Ave. SW, Washington, DC 20250, 202–604–0467.

SUPPLEMENTARY INFORMATION: This system of records covers information necessary and relevant to Department activities responding to and mitigating COVID–19 and other high-consequence public health threats, and diseases or illnesses relating to a public health emergency. Such information may include information on Department personnel, including employees, interns, contractors, and cooperators, who have contracted or may have been exposed to a suspected or confirmed disease or illness that is the subject of a declared public health emergency or who undergo preventative testing for, or receive a vaccination to prevent, a disease or illness that is the subject of a declared public health emergency, in accordance with federal, state, or local public health orders. The information collected may include identifying and contact information of individuals who have been suspected or confirmed to have contracted a disease or illness, or who have been exposed to an individual who had been suspected or confirmed to have contracted a disease or illness, related to a declared public health emergency; individual circumstances and dates of suspected exposure; testing results, symptoms, and treatments; vaccination records; health status information; and other information necessary and relevant to Department activities responding to and mitigating COVID–19 and other high-consequence public health threats and diseases or illnesses relating to a public health emergency. The Department maintains this information to understand the impact of an illness or disease on the Department workforce, and to assist in reducing the spread of the disease or illness among Department personnel. In certain instances, depending on the type of record collected and maintained, records maintained in this system of records may also be covered by Office of Personnel Management/Government-10 Employee Medical File System Records, 75 FR 35,099 (June 21, 2010). However, USDA/OSEC–01 covers additional records—specifically records collected in response to COVID–19, a high-consequence public health threat, as well as other declared public health emergencies.

When collecting information on Department employees, there are several employment laws that govern the collection, dissemination, and retention of employee medical information. These employment laws include the Americans with Disability Act (ADA), the Rehabilitation Act of 1973 (Rehab Act), and the Occupational Safety and Health Act of 1970 (OSH Act). Generally, under federal employment laws, medical information pertaining to employees is confidential and may be obtained by an employer only for certain reasons and only at certain points in the employment relationship. In response to a high-consequence public health threat such as COVID–19, or relating to other public health emergencies, an employer may be permitted to collect certain employee medical information that it would not otherwise be permitted to collect, depending upon the circumstances. This system of records will apply if it is determined that the circumstances permit the Department to legally collect the employee medical information at issue.

Further, this system of records notice (SORN) includes a reference to the Genetic Information Nondiscrimination Act of 2008 (GINA), 42 U.S.C. 2000ff to ff–11. Title II of GINA prohibits employment discrimination based on genetic information, including family medical history; restricts the circumstances under which employers may lawfully acquire applicants' and employees' genetic information; and prohibits the disclosure of applicants' and employees' genetic information, with limited exceptions, including those stated in 42 U.S.C. 2000ff–5(b) and 29 CFR 1635.9(b). The Department may request the circumstances of an individual's suspected or actual exposure to a disease or illness, including the source of exposure. Although it is not the intent for the Department to collect family medical information, an individual may indicate that they were exposed to specific family members who have been diagnosed with, or are suspected to have, the disease or illness in question. To the extent this information may be acquired inadvertently, such information will be kept as a ''confidential medical record'' and maintained separately from an employee's general medical files, pursuant to 42 U.S.C. 2000ff–5(a) and 29 CFR 1635.9(a).

In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and Congress on this new system of records. Dated: November 1, 2021. Sullie Coleman, Chief Privacy Officer United States Department of Agriculture.

SYSTEM NAME AND NUMBER:

USDA Personnel Public Health Emergency Records System, USDA/OSEC–01.

SECURITY CLASSIFICATION:

Controlled Unclassified Information.

SYSTEM LOCATION:

Micro-Soft (MS) 365 Multi-Tenant (MT) provides Exchange and SharePoint Access for USDA Personnel Public Health Emergency Records. Tenant locations are defaulted to Geo based on the country. In the United States, these records may be maintained electronically at one or more of Microsoft Data Centers, including, but not limited to, Boydton, Virginia and Cheyenne, Wyoming. The agency, US Department of Agriculture, address is 1400 Independence Ave. SW, Washington, DC 20250 and the address of the third-party service provider is Microsoft, 1 Microsoft Way, Redmond, Washington 98052–6399.

SYSTEM MANAGER:

Contact information of the agency official who is responsible for this system is USDA OCIO–CEC MS 365 Program Manager, 2312 E Bannister Road, Mail Stop 9198, Kansas City, MO 64114, 816–926–6860.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970, Executive Order No. 12,196, Occupational safety and health programs for Federal employees, 5 U.S.C. 7902; federal laws related to a specific public health emergency or high-consequence public health threat, including, (1) Executive Order No. 13994, Ensuring a Data-Driven Response to COVID–19 and Future High-Consequence Public Health Threats, (2) Executive Order 14043, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees, (3) Executive Order 12196, Occupational Safety and Health Program for Federal Employees, (4) 5 U.S.C. chapters 33 and 63, (5) the Soil Conservation and Domestic Allotment Act (16 U.S.C. 590h) as amended, 5 U.S.C. 8901 implemented at, 7 CFR part 7 and (6) federal laws that authorize the Attorney General to create and maintain federal records of agency activities, including 5 U.S.C. 301 and 44 U.S.C. 3101.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to maintain records necessary and relevant to Department activities responding to and mitigating COVID–19, other high consequence public health threats, or diseases and illnesses relating to a public health emergency. Such records include those records needed to understand the impact of an illness or disease on the Department workforce, and to assist in protecting the Department's workforce from, and responding to, a declared public health emergency or other high-consequence public health threats. Among other things, USDA may use the information collected to facilitate the provision of vaccines to USDA personnel, including employees, interns, contractors, and cooperators; to inform individuals who may have been in proximity of a person possibly infected with the disease or illness at or on buildings, grounds, and properties that are owned, leased, or used by the Department; or to confirm which personnel have received vaccinations to prevent such disease or illness to spread throughout the Department's workforce.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department personnel, including employees; non-Federal County Office (CO) employees in the Farm Service Agency (FSA) and elected or appointed FSA County and State Committee members; interns; contractors; and cooperators.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained in this system may include:

A. Full name, telephone number, worksite, email address, supervisor's name, address, and contact information and/or the contractor/cooperator's supervisor/contracting officer representative name, address, and contact information.

B. Date(s) and circumstances of the individual's suspected or actual exposure to disease or illness including symptoms, as well as locations within the Department workplace where an individual may have contracted or been exposed to the disease or illness.

C. Other individual information directly related to the disease or illness (*e.g.,* testing results/information, symptoms, treatments such as vaccines, and source of exposure).

D. Appointment scheduling information, including the date, time, and location of a scheduled appointment.

E. Medical screening information, including the individual's name, date of birth, age, category of employment, current medical status, vaccination history, and any relevant medical history.

F. Vaccination records, including the date, type, and dose of vaccine administered to the individual.

G. Records related to accommodations for exception for medical treatment or vaccinations.

RECORD SOURCE CATEGORIES:

Records may be obtained from USDA personnel, interns, contractors, and cooperators who may provide relevant information on a suspected or confirmed disease or illness, or the prevention of such disease or illness, which is the subject of a declared public health emergency. Information may also be sourced from personnel at medical facilities, or from existing systems of records, including but not limited to OPM/GOVT–10, Employee Medical File System Records, 75 FR 35,099 (June 21, 2010), and modified at 80 FR 74,815 (Nov. 30, 2015).

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 of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

A. To appropriate medical facilities, or federal, state, local, tribal, territorial, or foreign government agencies, to the extent permitted by law, for the purpose of protecting the vital interests of individual(s), including to assist the United States Government in responding to or mitigating high consequence public health threats, or diseases and illnesses relating to a public health emergency.

B. Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

C. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when the Department determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

D. To contractors, cooperators, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records.

E. To a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

F. To Federal, state, local, territorial, tribal, foreign, or international licensing agencies or associations which require information concerning the suitability or eligibility of an individual for a license or permit.

G. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

H. To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

I. To appropriate agencies, entities, and persons when

(1) the Department suspects or has confirmed that there has been a breach of the system of records.

(2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (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 the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

J. To another Federal agency or Federal entity, when the Department 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.

K. To any agency, organization, or individual for the purpose of performing authorized audit or oversight operations of the Department and meeting related reporting requirements.

L. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records in this system of records are maintained electronically and in paper and are in compliance with applicable executive orders, statutes, and agency implementing recommendations. Electronic records are stored in databases and/or on hard disks, removable storage devices, or other electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The Department will retrieve records by any of the categories of records, including, but not limited to, name, location, date of vaccination, or work status.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

To the extent applicable, to ensure compliance with Americans with Disabilities Act (ADA), the Rehabilitation Act, and the Genetic Information Nondiscrimination Act of 2008 (GINA), medical information must be ''maintained on separate forms and in separate medical files and be treated as a confidential medical record.'' 42 U.S.C. 12112(d)(3)(B); 42 U.S.C. sec 2000ff–5(a); 29 CFR 1630.14(b)(1), (c)(1), (d)(4)(i); and 29 CFR 1635.9(a). This means that medical information and documents must be stored separately from other personnel records. As such, the Department must keep medical records for at least one year from creation date. 29 CFR 1602.14. Further, records compiled under this SORN will be maintained in accordance with NARA General Records Schedule (GRS) 2.7, Items 010, 070 or 080, and NARA records retention schedules DAA–GRS2017–0010–0001, DAA–GRS2017–0010–0012, and DAA–GRS2017–0010–0013, to the extent applicable.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The Department safeguards records in this system according to applicable rules and polices, including all applicable USDA automated systems security and access policies. The Department has imposed strict controls to minimize the risk of compromising the information that is being stored. Users of individual computers can only gain access to the data by a valid user identification and password. Paper records are maintained in a secure, access-controlled room, with access limited to authorized personnel.

RECORD ACCESS PROCEDURES:

All requests for access to records must be in writing and should be addressed to the USDA Departmental FOIA Office, ATTN: Departmental FOIA Officer, 1400 Independence Avenue SW, South Building, Room 4104, Washington, DC 20250–0706, Email: *USDAFOIA@ocio.usda.gov*. The envelope and letter should be clearly marked ''Privacy Act Access Request.'' The request must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. The request must include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and either notarized or submitted under penalty of perjury. Additional details on procedures for access under the Privacy Act can be found in USDA Department Regulation 3515–002 Privacy Policy and Compliance for Personally Identifiable Information (PII) or at Privacy Policy and Compliance for Personally Identifiable Information (PII) (*usda.gov*).

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records maintained in this system of records must direct their requests to the address indicated in the ''RECORD ACCESS PROCEDURES'' paragraph, above. All requests to contest or amend records must be in writing and the envelope and letter should be clearly marked ''Privacy Act Amendment Request.'' All requests must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record. Additional details on procedures for contesting or amending records under the Privacy Act can be found in USDA Department Regulation 3515–002 Privacy Policy and Compliance for Personally Identifiable Information (PII) or at Privacy Policy and Compliance for Personally Identifiable Information (PII) (*usda.gov*).

NOTIFICATION PROCEDURES:

Individuals may be notified if a record in this system of records pertains to them when the individuals request

information utilizing the same procedures as those identified in the ''RECORD ACCESS PROCEDURES'' paragraph, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Sullie Coleman,

Chief Privacy Officer, United States Department of Agriculture.

[FR Doc. 2021–24370 Filed 11–5–21; 8:45 am]

BILLING CODE 3410–9R–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 requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments regarding this information collection received by December 8, 2021 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.

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.

Agricultural Research Service

Title: Meeting the Information Requirements of the Animal Welfare Act WorkshopRegistration Form.

OMB Control Number: 0518–0033.

Summary of Collection: The U.S. Department of Agriculture, National Agricultural Library (NAL), Animal Welfare Information Center conducts a workshop titled ''Meeting the Information Requirements of the Animal Welfare Act.'' The registration form collects information from interested parties necessary to register them for the workshop. This information includes workshop data preferences, signature, name, title, organization name, mailing address, phone and fax numbers and email address. The information will be collected using online and printed versions of the form. Also, forms can be fax or mailed.

Need and Use of The Information: NAL will collect information to register participants, contact them regarding schedule changes, control the number of participants due to limited resources and training space, and compile and customize class materials to meet the needs of the participants. Failure to collect the information would prohibit the delivery of the workshop and significantly inhibit NAL's ability to provide up-to-date information on the requirements of the Animal Welfare Act.

Description of Respondents: Individuals or Households; Not-for-Profit Institutions; Business or Other for-profit; Government; State, Local, or Tribal Government.

Number of Respondents: 270.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 22.

Dated: November 2, 2021.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–24297 Filed 11–5–21; 8:45 am]

BILLING CODE 3410–03–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 requested regarding: Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by December 8, 2021 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.

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.

Forest Service

Title: Storage and Use of Explosives and Magazine Security on National Forest System Lands Under a Special Use Authorization.

OMB Control Number: 0596–NEW.

Summary of Collection: Existing directives in the Forest Service Manual and Handbook are being revised to improve security and administration of explosive magazines and explosives use that are authorized under a special use authorization. The revisions clarify that all non-Forest Service storage and use of explosives, including use and storage of military weapons and ammunition for purposes of avalanche mitigation on National Forest System lands, must be authorized by a special use authorization that contains clause B–29 in Forest Service Handbook 2709.11, Chapter 50, section 52.2, on storage and use of explosives and magazine security. Clause B–29 requires authorization holders to comply with applicable United States Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives, state, or Department of

the Army requirements and applicable Forest Service requirements.

Need and Use of The Information: To allow the Forest Service to monitor holder compliance with clause B–29, the revised directives require holders of an authorization containing the clause to submit certain documentation annually as part of their operating plan. The required documentation includes copies of a log containing the date and type of magazine inspections (including inspections required every seven days) and the date all deficiencies identified in any magazine inspection report were corrected; copies of any magazine inspection reports; a copy of the holder's current ATF-issued federal explosives license or federal explosives permit, if applicable; and a copy of a log containing the date of the most recent magazine lock and key replacement.

Description of Respondents: Individuals or Households; Holders of a special use authorization authorizing the storage and use of explosives.

Number of Respondents: 60.

Frequency of Responses: Annually.

Total Burden Hours: 10.

Dated: November 2, 2021.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–24289 Filed 11–5–21; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0100]

Notice of Decision To Revise Requirements for the Importation of Fresh Melon Fruit From Japan Into the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are notifying the public of our decision to revise requirements for the importation of fresh melon fruit with stems from Japan into the United States. Based on the findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh melon fruit with stems from Japan into the entire United States.

DATES: Imports may be authorized at all U.S. ports beginning November 8, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Claudia Ferguson, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, Imports, Regulations, and Manuals, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2352.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in ''Subpart L-Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations provides requirements for authorizing the importation of fruits and vegetables into the United States and revising existing requirements for the importation of fruits and vegetables. Paragraph (c) of that section provides that the name and origin of all fruits and vegetables authorized for importation into the United States, as well as the requirements for their importation, be listed on the internet in APHIS' Fruits and Vegetables Import Requirements database, or FAVIR (*https://epermits.aphis.usda.gov/manual*). It also provides that, if the Administrator of APHIS determines that any of the phytosanitary measures required for the importation of a particular fruit or vegetable are no longer necessary to reasonably mitigate the plant pest risk posed by the fruit or vegetable, APHIS will publish a notice in the **Federal Register** making its pest risk documentation and determination available for public comment.

FAVIR had authorized the importation of fresh melon fruit without stems from Japan into Hawaii. The national plant protection organization of Japan, however, requested that we revise these import requirements to authorize importation of melons with stems into the entire United States.

Accordingly, in accordance with the process set forth in the regulations, we published a notice [1] in the **Federal Register** on May 21, 2021 (86 FR 27552–27553, Docket No. APHIS–2020–0100), in which we announced the availability, for review and comment, of a pest risk assessment (PRA) that evaluated the risks associated with allowing importation into the entire United States of fresh melon fruit with stems from Japan. Based on the PRA, we also prepared a risk management document to identify phytosanitary measures that could be applied to the fresh melon fruit with stems from Japan to mitigate the pest risk.

We solicited comments on the notice for 60 days ending July 20, 2021. We did not receive any comments.

Therefore, in accordance with the regulations in § 319.56–4(c)(3)(iii), we are announcing our decision to authorize the importation into the entire United States of fresh melon fruit with stems from Japan subject to the following revised phytosanitary measures:

- Fresh melon fruit with stems from Japan must be imported as commercial consignments only.
- Each consignment must be inspected and accompanied by a phytosanitary certificate issued by the Japanese national plant protection organization stating that the melon fruit with stems is free of cucumber green mottle mosaic virus.
- Each consignment is subject to inspection upon arrival in the United States.

These conditions will be listed in the FAVIR database (available at *https://epermits.aphis.usda.gov/manual*). In addition to these specific measures, fresh melon fruit with stems from Japan will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the recordkeeping and burden requirements associated with this action are included under the Office of Management and Budget control number 0579–0049.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E- Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this notice, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483.

[1] To view the notice and supporting documents, go to *www.regulations.gov* and enter APHIS–2020–0100 in the Search field.

Congressional Review Act

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

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 2nd day of November 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–24342 Filed 11–5–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Request for Information: Center for WIC Modernization and Delivery

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice: Request for information.

SUMMARY: The Food and Nutrition Service (FNS) is issuing this Request for Information (RFI) to gain insights from interested parties about establishing a resource center that supports State and local Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) agencies in improving the WIC application and certification journey.

This is a request for information that may inform a future cooperative agreement. It is not a solicitation for proposals or proposal abstracts. The purpose of this notice is to:

1. Determine the level of interest that exists for the proposed service;
2. Obtain information about the approach to providing the service, including needs, capabilities, and requirements; and
3. Gather information on the potential constraints and risks associated with this approach.

Information gathered through this RFI may be used to inform potential strategies for supporting and improving State and local WIC operations. FNS welcomes comments from all stakeholders.

DATES: Written comments must be received on or before December 8, 2021.

ADDRESSES: FNS is seeking information from a broad array of stakeholders—such as nonprofits, WIC State agencies, WIC local agencies, and others—about the Center for WIC Modernization and Delivery, the capabilities necessary to complete this work, relevant examples or case studies, and the capacity needed to support State and local WIC agencies. Responses to this RFI may be submitted by a single party or by a team.

USDA invites submission of the requested information through one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email:* FNS will accept electronic submissions emailed to [EMAIL]. The email should contain the subject line, ''Response to RFI: Center for WIC Modernization and Delivery.''

All comments submitted in response to this RFI will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. USDA will make the comments publicly available via *http://www.regulations.gov.*

Response to this RFI is voluntary. Respondents should respond to this RFI in a Microsoft Word document attached to email. This document should contain the following:

- Three clearly delineated sections: (1) Cover page with company name and contact information; (2) approach, no more than 10 single-spaced pages in length; and (3) business information.
- 1-inch margins (top, bottom, and sides).
- Times New Roman and 12 point font.

Privacy Note: All comments received from members of the public will be available for public viewing on *regulations.gov.*

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT: Sarah Widor, Director, Supplemental Food Programs Division at (703) 305–2746.

SUPPLEMENTARY INFORMATION:

I. Background

The American Rescue Plan Act of 2021 (ARPA; Pub. L. 117–2) provided $390 million in funding for WIC to carry out outreach, innovation, and program modernization efforts to increase WIC participation and redemption of benefits. See ARPA section 1106. Despite clear evidence that WIC drives better health outcomes, only about 57% of WIC-eligible mothers and children participated in the program in 2018. The funding provided through ARPA is a critical opportunity for WIC to undertake a range of high-impact projects to increase WIC's participation rate through an improved enrollment and participant experience, and to reduce disparities in program delivery.

Given this unprecedented opportunity to invest in programmatic innovations, FNS solicited input from a diverse range of stakeholders. FNS convened 27 listening sessions representing different stakeholder perspectives, interests, and geographies on ways to increase program participation and retention, improve the participant experience, streamline benefit delivery, and reduce disparities in program delivery. FNS also partnered with the U.S. Digital Service (USDS) to conduct research on how to improve the WIC certification process. This RFI is seeking information to build on that research.

FNS would like to partner with one or more organizations to create a Center for WIC Modernization and Delivery that will leverage human-centered design (HCD), modern technology practices, and data to improve the certification journey for WIC participants. This Center will be a resource for the 89 WIC State agencies (States, DC, territories, and Indian Tribal Organizations), and potentially WIC local agencies, to access cross-functional delivery capabilities to support digital transformation and service design initiatives. These capabilities might include data science, design, engineering, procurement, product management, and research expertise that states can leverage to develop and implement solutions aimed at improving WIC certification processes. The Center will work closely with FNS and USDS to define its approach and ensure solutions are practical, integrated into clinic practices, and drive towards a better participant journey through the WIC program and improved outcomes. FNS expects the Center to support WIC State agencies in improving enrollment and service delivery through a variety of ways, such as:

- Supporting State and local agencies in developing project ideas and proposals aimed at improving the participant journey and program outcomes;
- Helping State and local agencies use HCD, technology, and data more effectively in their clinic operations to increase enrollment and reduce disparities in program delivery;
- Assisting State and local agencies in addressing technical and/or service gaps; and

• Working with State and local agencies to implement holistic technology solutions and process changes. This might include helping them prototype, test, and iterate on potential solutions; and evaluating existing products or developing new ones for adoption by agencies. The Center might assist State and local agencies in procuring or implementing these solutions and measuring their impact on enrollment and retention.

Examples of solutions aimed at improving the applicant and participant experience may include:

• Participant-facing technology tools such as online schedulers, document uploaders, and participant portals;

• Data matching, interoperability, and/or cross-enrollment projects to reduce the documentation burden on participants;

• Technology platforms, which allow applicants to choose video, phone, text, or other voice applications to connect with WIC clinics;

• Content updates, such as content strategy or plain language updates to websites, forms, or notices;

• Data analytics tools; and

• Process improvements.

In addition to providing direct support to State and local agencies, FNS expects the Center to identify, evaluate, develop, and disseminate effective solutions and technical standards across States, and help WIC State agencies leverage their data to improve the WIC customer experience. It will also facilitate collaboration between WIC State agencies to address common operational issues.

FNS anticipates that the Center will support multiple WIC State agencies at once. The Center should have quick access to talent covering a spectrum of potential needs, and must be agile and capable of meeting shifting goals and objectives as they learn more about the problem space.

II. Responses

FNS is seeking information from stakeholders on the following questions. Responses should be limited to 10 single-spaced pages that follow the formatting guidelines above. Respondents should not include proprietary information or concepts in their responses.

FNS requests the following information:

(1) What capabilities should the Center have to effectively support State and local WIC agencies in implementing new technology solutions and process changes?

(2) How should the Center evaluate WIC State agency needs and prioritize projects?

(3) How should the Center work with State and local WIC agencies to help them modernize their WIC programs and improve the participant journey through WIC?

(4) How should the Center share and promote the reuse of best practices, solutions, code, reference implementations, and other resources among WIC State agencies to help them address common operational issues that impact the customer experience?

(5) How would you define and measure success for the Center?

(6) What risks do you foresee in establishing a Center to support WIC State agencies? How would you mitigate those risks?

(7) Do you have any other feedback or suggestions on this Center-based approach? Please describe in detail.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2021–24293 Filed 11–5–21; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Connecticut Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the Connecticut Advisory Committee to the U.S. Commission on Civil Rights will hold a meeting via web conference or phone call on Monday, December 6, 2021, at 12:00 p.m. The purpose of the web conference is to hear from experts on zoning issues in Connecticut.

DATES: December 6, 2021, Monday, at 12:00 p.m. (ET):

• To join by web conference, use WebEx link: *https://bit.ly/3pY6ROg;* password, if needed: USCCR–CT

• To join by phone only, dial 1–800–360–9505; Access Code: 2764 522 8107#

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez at *ero@usccr.gov* or by phone at 202–539–8246.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the WebEx link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing. may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided for this meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Barbara de La Viez at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 539–8246. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda: Monday, December 6, 2021, at 12:00 p.m. (ET)

I. Welcome and Roll Call
II. Web Conference on Zoning
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: November 3, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–24387 Filed 11–5–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Survey of Income and Program Participation

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 May 19, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: Survey of Income and Program Participation.

OMB Control Number: 0607–1000.

Form Number(s): None.

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 70,560.

Average Hours Per Response: 63 minutes.

Burden Hours: 74,088.

Needs and Uses: The SIPP collects information about a variety of topics including demographics, household composition, education, nativity and citizenship, health insurance coverage, Medicaid, Medicare, employment and earnings, unemployment insurance, assets, child support, disability, housing subsidies, migration, Old-Age Survivors and Disability Insurance (OASDI), poverty, and participation in various government programs like Supplemental Nutrition Assistance Program (SNAP), Supplemental Security Income (SSI), and Temporary Assistance for Needy Families (TANF). In the spring of 2021, as part of the American Rescue Plan, the child tax credit was expanded, and the Internal Revenue Service (IRS) was instructed to pay out monthly benefits. The 2022 SIPP instrument will collect receipt of the child tax credit payments.

The SIPP sample is nationally representative, with an oversample of low-income areas, in order to increase the ability to measure participation in government programs.

The SIPP program provides critical information necessary to understand patterns and relationships in income and program participation. It will fulfill its objectives to keep respondent burden and costs low, maintain high data quality and timeliness, and use a refined and vetted instrument and processing system. The SIPP data collection instrument maintains the improved data collection experience for respondents and interviewers and focuses on improvements in data quality and better topic integration.

Starting in 2019, the Census Bureau and the Social Security Administration (SSA) entered into a joint agreement where both agencies support the SIPP program by contributing resources to add, process, review, and maintain additional content on marital history, parental mortality, retirement and pension, and disability. This joint agreement started in September 2019 and goes until September 30, 2023.

The SIPP instrument is currently written in Blaise and C#. It incorporates an Event History Calendar (EHC) design to help ensure that the SIPP will collect intra-year dynamics of income, program participation, and other activities with at least the same data quality as earlier panels. The EHC is intended to help respondents recall information in a more natural ''autobiographical'' manner by using life events as triggers to recall other economic events. For example, a residence change may often occur contemporaneously with a change in employment. The entire process of compiling the calendar focuses, by its nature, on consistency and sequential order of events, and attempts to correct for otherwise missing data.

Since the SIPP EHC collects information using this ''autobiographical'' manner for the prior year, due to the coronavirus pandemic, select questions were modified to include answer options related to the pandemic as well as adding new questions pertaining to the pandemic. For instance, we adjusted the question regarding being away from work part-time to include being possibly furloughed due to coronavirus pandemic business closures. We also added new questions to collect information on whether the respondent received any stimulus payments.

Affected Public: Individual or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 141, 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–1000.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24369 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Current Population Survey, Annual Social and Economic Supplement

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on April 1, 2021, and on September 3, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: Current Population Survey, Annual Social and Economic Supplement.

OMB Control Number: 0607–0354.

Form Number(s): None.

Type of Request: Regular submission, Revision of a Currently Approved Collection.

Number of Respondents: 78,000.

Average Hours per Response: 0.41667.

Burden Hours: 32,500.

Needs and Uses: Information on work experience, personal income, noncash benefits, current and previous year health insurance coverage, employer-sponsored insurance take-up, and migration is collected through the ASEC. The work experience items in the ASEC provide a unique measure of the dynamic nature of the labor force as viewed over a one-year period. These items produce statistics that show movements in and out of the labor force by measuring the number of periods of unemployment experienced by people,

the number of different employers worked for during the year, the principal reasons for unemployment, and part-/full-time attachment to the labor force. We can make indirect measurements of discouraged workers and others with a casual attachment to the labor market. The ASEC data collection questions remain largely unchanged from its most recent collection in 2021, however, there are minor changes and additions requested. The changes are limited to questions on stimulus payments, free and reduced price school lunch, pandemic school meals, and advanced child tax credit payments.

The income data from the ASEC are used by social planners, economists, government officials, and market researchers to gauge the economic well-being of the country as a whole, and selected population groups of interest. Government planners and researchers use these data to monitor and evaluate the effectiveness of various assistance programs. Market researchers use these data to identify and isolate potential customers. Social planners use these data to forecast economic conditions and to identify special groups that seem to be especially sensitive to economic fluctuations. Economists use ASEC data to determine the effects of various economic forces, such as inflation, recession, recovery, and so on, and their differential effects on various population groups.

The ASEC is the official source of national poverty estimates calculated in accordance with the Office of Management and Budget's Statistical Policy Directive 14. Two other important national estimates derived from the ASEC are real median household income and the number and percent of individuals without health insurance coverage.

The ASEC also contains questions related to: (1) Medical expenditures; (2) presence and cost of a mortgage on property; (3) child support payments; and (4) amount of child care assistance received. These questions enable analysts and policymakers to obtain better estimates of family and household income, and more precisely gauge poverty status.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 141 and 182; and Title 29, United States Code, Sections 1–9.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0354.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24378 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE–29, Annual Survey of Foreign Ocean Carriers' Expenses in the United States

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 (PRA), on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 30, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis, Department of Commerce.

Title: Annual Survey of Foreign Ocean Carriers' Expenses in the United States.

OMB Control Number: 0608–0012.

Form Number(s): BE–29.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 80 annually (70 reporting mandatory data, and 10 that would file exemption claims or voluntary responses).

Average Hours per Response: 3 hours is the average for those reporting data and one hour is the average for those filing an exemption claim. Hours may vary considerably among respondents because of differences in company size and complexity.

Burden Hours: 220 hours annually.

Needs and Uses: The data are needed to monitor U.S. trade in transport services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in transport services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: U.S. agents of foreign ocean carriers.

Frequency: Annual.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0608–0012.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–24374 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[10/15/2021 through 10/28/2021]

Firm name	Firm address	Date accepted for investigation	Product(s)
Vita, Inc. d/b/a Vita Vibe d/b/a The Ballet Barre Store.	40 Ellwood Court, Greenville, SC 29607	10/15/2021	The firm manufactures ballet and fitness barres.
Helberg Electrical Supply, LLC	12B Filmore Place, Freeport, NY 11520	10/20/2021	The firm distributes electrical supplies and electrical power equipment.
Maximal Art, Inc. d/b/a John Wind	1610 South 8th Street, Philadelphia, PA 19148.	10/28/2021	The firm manufactures jewelry.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.8 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Bryan Borlik,

Director.

[FR Doc. 2021–24304 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–71–2021]

Foreign-Trade Zone (FTZ) 38—Spartanburg County, South Carolina; Notification of Proposed Production Activity; Swafford Warehousing, Inc. (Medical Kits); Greer, South Carolina

The South Carolina State Ports Authority, grantee of FTZ 38, submitted a notification of proposed production activity to the FTZ Board (the Board) on behalf of Swafford Warehousing, Inc., located in Greer, South Carolina under FTZ 38. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on November 1, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status materials/components and specific finished product, medical kits (duty-free), described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed foreign-status materials and components include: Lubricating jelly; catheters; alcohol-free sanitizing wipe sachets; burn film cling roll, plastic; chest drain kit (includes: Sutures, blunt forceps, chest drainage bag); hypodermic needles; sterile sutures; bandages, cotton adhesive; procedure masks; retractors; pocket bougies, endotracheal tubes; shielded intravenous (IV) catheters; instant ice packs; syringes; nasal cannulas; kinesiology tape; oxygen masks; gauze, sterile wound dressing, cotton mesh with paraffin wax blend; hygienic hand sanitizer; quick release tourniquets; sharpsafe boxes; sterile IV giving set for parenteral administration of infusions (IV fluids); forceps; film ported cannulas; glucometers; paper utility drapes; latex gloves; surgical cricothyrotomy sets (includes: Scalpels; syringes; tracheal tubes; extension tubing; tracheal hooks and neck tape); plastic nasal airway tubes with adjustable flange, latex-free; and, scalpels (duty rate ranges from duty-free to 5.3%). The request indicates that certain materials/components are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 20, 2021.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Diane Finver at *Diane.Finver@trade.gov.*

Dated: November 2, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–24305 Filed 11–5–21; 8:45 am]

BILLING CODE 3510–DS–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2021–0018]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Toy Warning Labels Online Survey

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required under the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission (CPSC or Commission) announces that CPSC has submitted to the Office of Management and Budget

(OMB) a new proposed collection of information for a survey to assess how toy safety labels on e-commerce websites affect caregivers' purchasing behaviors. On June 24, 2021, the CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of this collection of information. After reviewing and considering the comments, the Commission announces that it has submitted to the OMB a request for approval of this collection of information. A copy of the proposed survey, ''Revised Supporting Statement Toy Warning Survey'' is available at: *www.regulations.gov* under Docket No. CPSC–2021–0018, Supporting and Related Material.

DATES: Submit written or electronic comments on the collection of information by December 8, 2021.

ADDRESSES: Send written comments and recommendations for the proposed information collection within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 30-day Review—Open for Public Comments,'' or by using the search function. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2021–0018.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3520), federal agencies must obtain approval from 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 data-collection studies and surveys. Agencies must provide notice of the proposed collection of information in the **Federal Register**, and provide a 60-day comment period, before submitting the collection to OMB for approval. 44 U.S.C. 3506(c)(2)(A). Agencies then must evaluate any public comments and publish another notice in the **Federal Register**. *Id.* 3507(a)(1).

In accordance with these procedures, on June 24, 2021, CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of a new collection of information on a survey on the Toy Warning Labels Online Survey. 86 FR 33239. Section B. Comments, below, summarizes and addresses the comments CPSC received.

A. Toy Warning Labels Online Survey

CPSC is authorized under section 5(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2054(a), to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. Section 5(b) of the CPSA, 15 U.S.C. 2054(b), further provides that CPSC may conduct research, studies, and investigations on the safety of consumer products, and develop product safety test methods and testing devices.

In 2020, CPSC conducted an Online Shopping Focus Group with 40 participants, which was approved under OMB Control No. 3041–0136. In-depth interviews were conducted with primary caregivers (parent or guardian) of young children ages 3 to 6 years old, to gather feedback on the caregivers' understanding, perceptions, and attitudes toward online toy safety messaging. Caregiver responses in the focus group study indicated that typically, they do not look for warning labels on web pages when shopping for toys on e-commerce websites. Some of the reasons for their failure to look for the warning labels may be the lack of prominent visibility of the safety information on consumer web pages, or because the warning labels were not particularly noticeable, or easy to find. These findings suggest that improving the location or design of warning labels may help caregivers become more aware and informed about the potential safety risks associated with products intended for young children.

CPSC seeks to learn more about caregivers' understanding and awareness of warning labels for toys intended for children 2 to 6 years old. This proposed survey will augment the work conducted in the focus group, through an online survey. The proposed survey will be directed to caregivers who have purchased a toy from an e-commerce website for a 2- to 6-year-old child and assess how these caregivers interpret and adhere to safety warnings when purchasing toys for their child. CPSC will use this information to develop strategies and best-practice approaches for recommending where and how safety warnings for children's products should be displayed to get caregivers' attention when shopping online for children's toys or products.

CPSC has contracted with Fors Marsh Group, LLC, to develop and execute this project for CPSC. Information obtained through this survey is not intended to be considered nationally representative. CPSC intends to use findings from this survey, with findings from other research and activities, to assist with providing recommendations for refining and enhancing warning labels in the future, to convey critical information effectively about product safety warnings for online sellers.

B. Comments

CPSC received one comment in response to the June 24, 2021 notice. The commenter stated support for the research. However, the commenter raised a concern that the small sample size of 250 will not provide enough information and stated that an increased sample size, such as 500, would provide more insights. Commenter also suggested making efforts to get a diverse range of shoppers in the sample, in terms of income, race, and other demographic information, as well as in terms of familiarity with shopping and purchasing online. The commenter expressed the belief that first-time shoppers for an online children's product will have different responses from regular online shoppers. Furthermore, the commenter recommends that CPSC, while conducting the survey, seek information on different types of products that parents shop for online.

CPSC considered the comment and modified the survey to increase the sample size of the survey from 250 to 750 participants. The survey will screen participants to ensure the selection of a sample that varies on income, education, caregiver age, age of their child(ren), and other parameters. The panel provider will also monitor respondents to ensure that underserved populations are represented in the sample and that insights are collected from a diverse population. Although the survey instrument will differentiate results between first-time and regular online shoppers, the purpose of the survey is to gather feedback on the caregivers' understanding, perceptions, and attitudes toward online toy safety messaging information, rather than on the different types of products parents shop for online. However, the Commission may consider additional research to collect this information in the future.

C. Burden Hours

We revised the estimate of the number of respondents to the survey from 250 to 750 participants. The online survey for the proposed study will take approximately 15 minutes (0.25 hours) to complete. We estimate the total

annual burden hours for respondents to be 187.50 hours. The monetized hourly cost is $38.60, as defined by total compensation for all civilian workers, U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, as of December 2020. Accordingly, we estimate the total cost burden to be $7,237.50 (187.50 hours × $38.60). The total cost to the federal government for the contract to design and conduct the proposed survey is $152,712.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2021–24363 Filed 11–5–21; 8:45 am]

BILLING CODE P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2021–0020]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazard Warning Communication Survey

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval for an information collection on a proposed survey to assess how hazard warnings are communicated to consumers. On July 26, 2021, the CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of this collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of this collection of information, without change.

DATES: Submit written or electronic comments on the collection of information by December 8, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2021–0020.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION: On July 26, 2021, the Commission published notice of the proposed collection on the hazard warning communication survey. 86 FR 40018. The Commission did not receive any comments. Accordingly, the Commission announces that it has submitted to the OMB a request for approval of this collection, without change.

A. Hazard Warning Communication Survey

CPSC is authorized under section 5(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2054(a), to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. Section 5(b) of the CPSA, 15 U.S.C. 2054(b), further provides that CPSC may conduct research, studies, and investigations on the safety of consumer products, and develop product safety test methods and testing devices.

CPSC proposes to conduct an online survey to gather data on consumer risk perception and response to hazard communications from 5,000 respondents. The study population will be comprised of individuals age 18 and over from across the United States. In this proposed survey, CPSC seeks information about consumer product use, including, but not limited to, the following topics:

- Consumers' beliefs, experiences, and tendencies regarding product safety;
- whether consumers pay attention to instructions that come with products;
- whether consumers read safety information and labels;
- to what extent consumers comply with safety messages;
- how product type influences consumers' attitude and behavior;
- what information resources consumers rely on before buying a product;
- how product safety ranks among other factors consumers consider;
- reasons consumers comply or do not comply with the safety messages; and
- how consumers respond if they encounter a safety recall of the product they own.

CPSC has contracted with Carahsoft/Qualtrics to develop and execute this project for CPSC. Information obtained through this survey is not intended to be considered nationally representative. The panel provider will monitor respondents, and if a particular demographic is trending highly, the panel provider will slow down the sample for that segment and will focus on obtaining responses from others to ensure recruitment for U.S. census-matched survey participants from the Midwest, Northeast, South, and West regions. The panel provider will also monitor respondents to ensure that underserved populations are represented in the sample and that insights are collected from a diverse population.

CPSC intends to use the study findings to develop a better understanding of the mechanisms and types of safety messages that consumers receive, how they respond, and what affects their response. Specifically, responses to the items in this survey will provide CPSC staff with information on whether consumers read and comply with various types of safety information that comes with products they use; the causes of consumer noncompliance with product safety information; whether consumers share product safety information with other users of their products; what sources of information they rely on to decide if a product is safe to use; whether safety is a priority in their purchasing decisions; how they responded to safety notices and recalls in the past; reasons for noncompliance with safety notices and recalls; and if and how the product type affects their risk perception and behaviors. Findings from this survey will provide CPSC with information on ways to increase consumer understanding of, and adherence to, safety messaging and help CPSC develop more effective messaging that will convey critical information about product hazards.

B. Burden Hours

We estimate the number of respondents to the survey to be 5,000. The online survey for the proposed study will take approximately 15 minutes (0.25 hours) to complete. We estimate the total annual burden hours for respondents to be 1,250 hours. The monetized hourly cost is $38.60, as defined by total compensation for all civilian workers, U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, as of December 2020. Accordingly, we estimate the total cost burden to be $48,250 (1,250 hours × $38.60). The total cost to the federal

government for the contract to design and conduct the proposed survey is $150,978.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2021–24358 Filed 11–5–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

[Docket ID ED–2021–IES–0154]

Request for Information on Rigorous Research on Interventions That Promote Postsecondary Success

AGENCY: Institute of Education Sciences, Department of Education.

ACTION: Request for information.

SUMMARY: The What Works Clearinghouse, a program of the U.S. Department of Education's Institute of Education Sciences, reviews existing research on education policies, programs, products, and practices to provide educators and other key stakeholders the information they need to make evidence-based decisions. Through this request for information (RFI), the What Works Clearinghouse seeks public input to help us find rigorous research on education practices designed to improve postsecondary student success.

DATES: We must receive your comments by December 8, 2021.

ADDRESSES: Submit your response to this RFI through the Federal eRulemaking Portal. We will not accept submissions by postal mail, commercial mail, hand delivery, fax, or email. To ensure that we do 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 the ''FAQ'' tab.

Privacy Note: The Department's policy for comments received from members of the public is to make these submissions 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. We encourage, but do not require, that each respondent include his or her name, title, institution or affiliation, and the name, title, mailing and email addresses, and telephone number of a contact person for his or her institution or affiliation, if any.

FOR FURTHER INFORMATION CONTACT: Matthew Soldner, Commissioner, National Center for Education Evaluation and Regional Assistance & Evaluation Officer, Institute of Education Sciences, U.S Department of Education, 400 Maryland Avenue SW, Room 4160, Potomac Center Plaza, Washington, DC 20202–7240. Telephone: (202) 245–8385. Email: *Matthew.Soldner@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

A sizable number of students who enter postsecondary education with the intention of earning a certificate or degree never achieve that goal. One out of every five (18.5 percent) first-time postsecondary students who entered college in 2011–12 with the goal of completing a bachelor's degree had not earned a credential of any type (completion) and was no longer enrolled (persistence) by spring 2017. Among students who entered college in 2011–12 and had intended to earn an associate degree, the combined persistence and completion rate was even lower: nearly half (45.7 percent) were no longer enrolled and had no education credential to show for their time, effort, and expense.[1]

There is unlikely to be a ''one size fits all'' solution to significantly improving postsecondary completion outcomes among the Nation's learners, given their diversity and the diversity of institutions they attend. Instead, a variety of policies, programs, products, and practices will be needed. What should be common across all, however, is that they should be evidence-based.

The What Works Clearinghouse (WWC), a program of the U.S. Department of Education's Institute of Education Sciences, reviews existing education research to provide educators and other key stakeholders information they can use to make evidence-based decisions. Specifically, the WWC reviews causal impact studies; that is, research evaluating the efficacy of interventions—policies, programs, products, or practices—on outcomes of interest.

Since 2012, the WWC has sought to increase the number of causal impact studies it has reviewed that are relevant to postsecondary educators, policymakers, and administrators. To date, this includes more than 930 individual studies.[2] In that same time, the WWC has tripled the number of systematic reviews it conducts of specific branded and non-branded interventions (Intervention Reports)[3] and expanded its portfolio of postsecondary-focused Practice Guides,[4] publications that present specific, evidence-based recommendations for educators to improve their practice.

Despite the growth in its postsecondary-focused resources, the Department believes there may be existing causal impact research specifically relevant to improving postsecondary completion outcomes among the Nation's learners that the WWC has not yet reviewed. As such, we seek public comment to assist us in identifying relevant research. We are particularly interested in research that focuses on policies, programs, products, and practices that improve postsecondary success and can be implemented by postsecondary systems and/or institutions, working either in their own settings or in other settings (*e.g.,* high schools) in partnership with other education stakeholders (*e.g.,* local or State educational agencies).

This is a request for information only. This RFI is not a request for proposals (RFP) or a promise to issue an RFP or a notice inviting applications. This RFI does not commit the Department to contract for any supply or service whatsoever. Further, we are not seeking proposals and will not accept unsolicited proposals. The Department will not pay for any information or administrative costs that you may incur in responding to this RFI. The documents and information submitted in response to this RFI will not be returned.

We will review every comment, and, as described above, electronic comments in response to this RFI will be publicly available on the Federal eRulemaking Portal at

[1] See Table 1.1–C in *Web Tables—A 2017 Follow-up: Six-Year Persistence and Attainment at Any Institution for 2011–12 First-Time Postsecondary Students* (NCES 2020–238). *https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2020238.*

[2] See *https://go.usa.gov/xMsKy* to see individual studies reviewed by the WWC in the postsecondary topic area.

[3] See *https://go.usa.gov/xMsKM* to see WWC Intervention Reports in the postsecondary topic area.

[4] See *https://go.usa.gov/xMsKz* to see WWC Practice Guides in the postsecondary topic area.

www.regulations.gov. Please note that IES will not directly respond to comments.

Solicitation of Comments

We invite stakeholders who are aware of publicly available causal impact research that is specifically relevant to improving postsecondary completion outcomes among the Nation's learners but that the WWC has not yet reviewed to share the following in their comments:

(1) The work's author, title, year of publication, and publisher; and

(2) If available, the work's Digital Object Identifier (DOI), ERIC number, or a URL where the WWC can find a publicly available copy of the work (*e.g.,* a university website).

Commenters should not include manuscripts in their submissions that are not publicly available.

The Institute is committed to improving the public's access to, and the discoverability of, education research. In service of that goal, we invite authors, those who hold copyright, or their authorized representatives to consider depositing eligible content into ERIC, the Institute of Education Sciences' bibliographic and full-text database of education research (*https://eric.ed.gov/*). More information about submitting content to ERIC, including our selection policy and how to access the online submission portal, can be found at *https://eric.ed.gov/submit/.*

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.

Matthew Soldner,

Commissioner, National Center for Education Evaluation and Regional Assistance & Agency Evaluation Officer.

[FR Doc. 2021–24382 Filed 11–5–21; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meetings

AGENCY: U.S. Election Assistance Commission.

ACTION: Sunshine Act notice; notice of public meeting agenda.

SUMMARY: Roundtable Discussion: E-Poll Book Testing Pilot Program Considerations.

DATES: Wednesday, November 17, 2021, 1:00 p.m.–3:30 p.m. Eastern.

ADDRESSES:

Virtual via Zoom

The roundtable discussion is open to the public and will be livestreamed on the U.S. Election Assistance Commission YouTube Channel: *https://www.youtube.com/channel/UCpN6i0g2rlF4ITWhwvBwwZw*

FOR FURTHER INFORMATION CONTACT: Kristen Muthig, Telephone: (202) 897–9285, Email: *kmuthig@eac.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Government in the Sunshine Act (Sunshine Act), Public Law 94–409, as amended (5 U.S.C. 552b), the U.S. Election Assistance Commission (EAC) will conduct a virtual roundtable discussion on considerations for the establishment of a testing pilot program for electronic poll books (e-poll books).

Agenda: The U.S. Election Assistance Commission (EAC) will hold a roundtable discussion on the benefits and challenges of implementing a testing program for e-poll books. The event will include three panels representing election officials, e-poll book manufacturers, and technology experts.

An increasing number of election jurisdictions are utilizing e-poll books, replacing or supplementing the use of traditional paper poll books that contain and track voter rolls. Thirteen states where e-poll books are used have a certification program, and 12 states do not. The EAC recognized the need for uniform certification and testing standards and is in the process of developing a pilot program for e-poll books to enhance the security, as well as accessibility, of these devices. This public meeting will help the EAC identify opportunities, challenges, and continuing needs of election officials who use these systems, the manufacturers who develop them, and experts who have an additional understanding of this subject.

The full agenda will be posted in advance on the EAC website: *https://www.eac.gov.*

Status: This roundtable discussion will be open to the public.

Kevin Rayburn,

General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2021–24481 Filed 11–4–21; 4:15 pm]

BILLING CODE P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Wednesday, December 15, 2021; 9:00 a.m.–4:30 p.m.

Thursday, December 16, 2021; 9:00 a.m.–4:30 p.m.

ADDRESSES: Online Virtual Meeting. To receive the meeting access information and call-in number, please contact the Federal Coordinator, Gary Younger, at the telephone number or email listed below by five days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Gary Younger, Federal Coordinator, U.S. Department of Energy, Hanford Office of Communications, Richland Operations Office, P.O. Box 550, Richland, WA 99354; Phone: (509) 372–0923; or Email: *gary.younger@rl.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Discussion Topics
  - Tri-Party Agreement Agencies' Updates
  - Hanford Advisory Board Committee Reports
  - Board Business

Public Participation: The meeting is open to the public. The EM SSAB, Hanford, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gary Younger at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or within five business days after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Gary Younger. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available at the following website: *http://www.hanford.gov/page.cfm/hab/FullBoardMeetingInformation.*

Signed in Washington, DC, on November 2, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–24332 Filed 11–5–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ22–2–000]

City of Vernon, California; Notice of Filing

Take notice that on November 1, 2021, the City of Vernon, California submitted its tariff filing: Revised Transmission Revenue Requirement and Transmission Revenue Balancing Account Adjustment with an effective date of January 1, 2022.

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.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on November 22, 2021.

Dated: November 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24352 Filed 11–5–21; 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: CP22–10–000.
Applicants: Southern Natural Gas.
Description: Application for Authorization of Abonnement for Rate Schedule X–74 of Southern Natural Gas Company, L.L.C.
Filed Date: 10/26/21.
Accession Number: 2021026–5033.
Comment Date: 5 p.m. ET 11/16/21.

Docket Numbers: RP21–778–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Motion Filing: Rate Case (RP21–778) Motion Filing to be effective 11/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5251.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–131–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (SoCal) to be effective 11/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5170.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–132–000.
Applicants: OkTex Pipeline Company, L.L.C.
Description: Compliance filing: 2020—2021 Gas Sales and Purchase Report to be effective N/A.
Filed Date: 10/29/21.
Accession Number: 20211029–5178.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–133–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2021–10–29 Negotiated Rate Agreements to be effective 11/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5180.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–134–000.
Applicants: Golden Triangle Storage, Inc.
Description: § 4(d) Rate Filing: GTS No-Notice Firm Storage Service to be effective 12/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5181.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–135–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: § 4(d) Rate Filing: Capacity Allocation—Interruptions of Service to be effective 12/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5185.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–136–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 11–1–2021 to be effective 11/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5196.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–137–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Tariff Records for New Pooling Locations to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5213.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–138–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Nov 2021 to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5224.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–139–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Clean-Up Filing to be effective 11/2/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5246.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–140–000.

Applicants: Elba Express Company, L.L.C.

Description: § 4(d) Rate Filing: Measurement Filing to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5248.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–141–000.

Applicants: Guardian Pipeline, L.L.C.

Description: Compliance filing: 2020—2021 Gas Sales and Purchase Report to be effective N/A.

Filed Date: 10/29/21.

Accession Number: 20211029–5253.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–142–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: TETLP PCB DEC 2021 Filing to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5259.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–143–000.

Applicants: Midwestern Gas Transmission Company.

Description: Compliance filing: 2020—2021 Gas Sales and Purchase Report to be effective N/A.

Filed Date: 10/29/21.

Accession Number: 20211029–5266.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–144–000.

Applicants: Midwestern Gas Transmission Company.

Description: Compliance filing: 2020—2021 Cash Out Report to be effective N/A.

Filed Date: 10/29/21.

Accession Number: 20211029–5270.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–145–000.

Applicants: Elba Express Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Clean-up Filing to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5277.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–146–000.

Applicants: Viking Gas Transmission Company.

Description: Compliance filing: 2020—2021 Gas Sales and Purchase Report to be effective N/A.

Filed Date: 10/29/21.

Accession Number: 20211029–5282.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–147–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Agreements Effective 11/1/2021 to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5289.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–148–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: § 4(d) Rate Filing: TPC 2021–10–29 Negotiated Rate Agreements and Amendment to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5351.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–149–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: TETLP ASA DEC 2021 FILING to be effective 12/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5002.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–150–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 11–1–2021 to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5004.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–151–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 11–1–2021 to be effective 11/1/2021..

Filed Date: 11/1/21.

Accession Number: 20211101–5008.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–152–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Various 11–1–2021 Releases to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5030.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–153–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed 910950 Releases 11–1–2021 to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5031.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–154–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—11/1/2021 to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5032.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–155–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—ConEd 911792 Releases 11–1–2021 to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5033.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–156–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 11.1.21 Negotiated Rates—TM Energy Atlantica Inc. H–8085–89 to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5052.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–157–000.

Applicants: Equitrans, L.P.

Description: Compliance filing: Operational Purchases and Sales Report for 2021 to be effective N/A..

Filed Date: 11/1/21.

Accession Number: 20211101–5060.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–158–000.

Applicants: Rover Pipeline LLC.

Description: Compliance filing: RVR Cost and Revenue Study in Compliance with CP15–93–000 and CP15–93–001 Order to be effective N/A.

Filed Date: 11/1/21.

Accession Number: 20211101–5079.

Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–159–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Non-conforming—Twin Eagle, Castleton, and Sequent to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5080.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–160–000.
Applicants: WBI Energy Transmission, Inc.
Description: § 4(d) Rate Filing: 2021 Negotiated & Non-Conforming SA with ONEOK to be effective 12/2/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5081.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–161–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Kaiser Mktg 35448 to Kaiser Appalachian 39247) to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5092.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–162–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Constellation 54459 to Exelon 54487) to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5103.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–163–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Marathon 51753, 51754 to Spire 54462, 54465) to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5104.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–164–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Osaka 46429 to Texla 54503) to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5105.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–165–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: Annual Fuel Retention Adjustment of Destin Pipeline Company, L.L.C.
Filed Date: 11/1/21.
Accession Number: 20211101–5111.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–166–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Compliance filing: NAESB Version 3.2 Compliance Filing to be effective 6/1/2022.
Filed Date: 11/1/21.
Accession Number: 20211101–5141.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–167–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Nov 1 Capacity Releases to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5156.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–168–000.
Applicants: Stagecoach Pipeline & Storage Company LLC.
Description: Compliance filing: NAESB Version 3.2 Compliance Filing to be effective 6/1/2022.
Filed Date: 11/1/21.
Accession Number: 20211101–5157.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–169–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Contract Renewal Revisions to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5160.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–170–000.
Applicants: Arlington Storage Company, LLC.
Description: Compliance filing: NAESB Version 3.2 Compliance Filing to be effective 6/1/2022.
Filed Date: 11/1/21.
Accession Number: 20211101–5162.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–171–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: 2021 Fuel Tracker Filing to be effective 4/1/2022.
Filed Date: 11/1/21.
Accession Number: 20211101–5185.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–172–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated rate—Con Edison to Marathon Release to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5192.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–173–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Non-conforming—ConEd 911792 to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5202.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–174–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: § 4(d) Rate Filing: TPC 2021–11–01 Negotiated Rate Agreement to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5247.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–175–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: ANR-Koch NR Agreement No. 136283 to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5257.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–176–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Amendment to a Negotiated Rate Agreement Filing-Presidio Finance LLC to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5259.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–177–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Non-conforming—BUG 911814 to be effective 11/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5266.
Comment Date: 5 p.m. ET 11/15/21.

Docket Numbers: RP22–178–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Non-conforming—Chesapeake 911801 and 911802 to be effective 11/1/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5001.
Comment Date: 5 p.m. ET 11/15/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP20–1060–005.
Applicants: Columbia Gas Transmission, LLC.
Description: Compliance filing: Stipulation and Agreement of Settlement RP20–1060 et al. to be effective N/A.
Filed Date: 10/29/21.

Accession Number: 20211029–5228.
Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP21–100–005.
Applicants: National Grid LNG, LLC.
Description: Compliance filing: 2021–10–29 Compliance Filing to Implement Settlement Tariff Sheets to be effective 5/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5212.
Comment Date: 5 p.m. ET 11/10/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24355 Filed 11–5–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–296–000]

Jackson Generation, 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 Jackson Generation, 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 November 22, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: November 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24353 Filed 11–5–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–12–000.
Applicants: Calhoun Power Company, LLC, Alabama Power Company.
Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Calhoun Power Company, LLC, et al.
Filed Date: 10/29/21.
Accession Number: 20211029–5156.
Comment Date: 5 p.m. ET 12/28/21.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–8–000.
Applicants: Irradiant Partners, LP.
Description: Petition for Declaratory Order of Irradiant Partners, LP.
Filed Date: 11/1/21.
Accession Number: 20211101–5313.
Comment Date: 5 p.m. ET 12/1/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–2498–001.
Applicants: Versant Power.
Description: Compliance filing: Amend Order No. 676–I Compliance Filing and Request for Waivers to be effective 12/31/9998.
Filed Date: 11/1/21.
Accession Number: 20211101–5250.
Comment Date: 5 p.m. ET 12/1/21.

Docket Numbers: ER22–46–001.
Applicants: Parkway Generation Essex, LLC.
Description: Tariff Amendment: Submission of Additional Information to be effective 12/1/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5162.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–312–000.
Applicants: Broad River Energy LLC.
Description: Petition for Limited Waiver of Broad River Energy LLC.
Filed Date: 10/29/21.
Accession Number: 20211029–5389.
Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–314–000.
Applicants: AEP Texas Inc.
Description: § 205(d) Rate Filing: AEPTX–El Sauz Ranch Wind 1st A&R Generation Interconnection Agreement to be effective 10/14/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5080.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–315–000.
Applicants: Idaho Power Company.
Description: Tariff Amendment: Cancellation of Rate Schedule 167 to be effective 12/31/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5101.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–316–000.
Applicants: Idaho Power Company.

Description: Initial rate filing: RS 170—NorthernGrid Funding Agreement 2022–2023 to be effective 1/1/2022.
Filed Date: 11/2/21.
Accession Number: 20211102–5102.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–317–000.
Applicants: LS Power Marketing, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 11/3/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5121.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–318–000.
Applicants: Bolt Energy Marketing, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 11/3/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5122.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–319–000.
Applicants: Columbia Energy LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 11/3/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5123.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–320–000.
Applicants: LifeEnergy, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 11/3/2021.
Filed Date: 11/2/21.
Accession Number: 20211102–5124.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–321–000.
Applicants: Basin Electric Power Cooperative.
Description: § 205(d) Rate Filing: Submission of Revised Wholesale Power Contract FERC Rate Schedule No. 9 to be effective 1/1/2022.
Filed Date: 11/2/21.
Accession Number: 20211102–5149.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–322–000.
Applicants: Startrans IO, LLC.
Description: § 205(d) Rate Filing: TRBAA 2022 Update to be effective 1/1/2022.
Filed Date: 11/2/21.
Accession Number: 20211102–5153.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–323–000.
Applicants: Exelon Generation Company, LLC.
Description: § 205(d) Rate Filing: Nuclear Operating Services Agreements Filing to be effective 12/31/9998.
Filed Date: 11/2/21.
Accession Number: 20211102–5160.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–324–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Notice of Cancellation of Service Agreement Nos. 2274 & 2275 (PJM & AEC NITSA) to be effective 1/1/2022.
Filed Date: 11/2/21.
Accession Number: 20211102–5164.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–325–000.
Applicants: Calvert Cliffs Nuclear Power Plant, LLC.
Description: § 205(d) Rate Filing: Certificate of Concurrence for Nuclear Operating Services Agreement to be effective 12/31/9998.
Filed Date: 11/2/21.
Accession Number: 20211102–5167.
Comment Date: 5 p.m. ET 11/23/21.

Docket Numbers: ER22–326–000.
Applicants: Exelon FitzPatrick, LLC.
Description: § 205(d) Rate Filing: Certificate of Concurrence for Nuclear Operating Services Agreement to be effective 12/31/9998.
Filed Date: 11/2/21.
Accession Number: 20211102–5173.
Comment Date: 5 p.m. ET 11/23/21.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–18–000.
Applicants: Portland General Electric Company.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Portland General Electric Company.
Filed Date: 10/29/21.
Accession Number: 20211029–5392.
Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ES22–19–000; ES22–20–000; ES22–21–000; ES22–22–000.
Applicants: Entergy Arkansas, LLC, Entergy Mississippi, LLC, Entergy Texas, Inc., System Energy Resources, Inc.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Entergy Arkansas, LLC, et al.
Filed Date: 10/29/21.
Accession Number: 20211029–5393.
Comment Date: 5 p.m. ET 11/19/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 02, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24354 Filed 11–5–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Wednesday, November 17, 2021, from 10:00 a.m. to 3:00 p.m.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland, 20857, (301) 427–1456. For press-related information, please contact Bruce Seeman at (301) 427–1998 or *Bruce.Seeman@AHRQ.hhs.gov.* Closed captioning will be provided during the meeting. If another reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827–4840, no later than Monday, November 8, 2021. The agenda, roster, and minutes will be available from Ms. Heather Phelps, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland, 20857. Ms. Phelps' phone number is (301) 427–1128.

SUPPLEMENTARY INFORMATION:

I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App., this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). The Council is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Wednesday, November 17, 2021, the Council meeting will convene at 10:00 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting will begin with an introduction of new NAC members and then an update on AHRQ's Subcommittee of the National Advisory Council (SNAC) on Healthcare Quality Measurement. The agenda will also include a discussion on primary care. The meeting will adjourn at 3:00 p.m.

The meeting is open to the public. For information regarding how to access the meeting as well as other meeting details, including information on how to make a public comment, please go to *https://www.ahrq.gov/news/events/nac/.* The final agenda will be available on the AHRQ website no later than Thursday, November 11, 2021.

Dated: November 2, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–24296 Filed 11–5–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis (ACET)

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 CDC announces the following meeting of the Advisory Council for the Elimination of Tuberculosis Meeting (ACET). This meeting is open to the public and limited to 1,000 audio and web conference lines. Time will be available for public comment.

DATES: The meeting will be held on December 14, 2021, from 10:00 a.m. to 3:45 p.m., EST, and December 15, 2021, from 10:00 a.m. to 12:00 p.m., EST.

The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed below. In the subject line, please note ATTN: Staci Morris for ACET Public Comment. The public comment should include your name, affiliation, and email address.

Comments must be received on or before December 13, 2021.

ADDRESSES: The web conference access is:

https://cdc.zoomgov.com/j/1612312595?pwd=WnhzbDdEZGJIQXc1UkhoN2sxU05IUT09.

Passcode: H&0uhKFm.

Webinar ID: 161 231 2595.

The teleconference access is noted as follows:

Telephone number: 1–669–254–5252; and the passcode is 49252654.

FOR FURTHER INFORMATION CONTACT: Staci Morris, Committee Management Specialist, National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, 1600 Clifton Road NE, Mailstop US8–6, Atlanta, Georgia 30329–4027; Telephone: (404) 718–7479; Email: *nchhstppolicy@cdc.gov.* (In the subject line, please note ATTN: Staci Morris for ACET Public Comment).

SUPPLEMENTARY INFORMATION:

Purpose: The Council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis (TB). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Considered: The agenda will include discussions on: (1) Study 31 Regimen Guidance; (2) TB Epidemiologic Studies Consortium; (3) Latent Tuberculosis Infection (LTBI) Campaign; (4) NCHHSTP and Division of Tuberculosis Elimination Equity Activities; (5) Electronic Directly Observed Therapy (eDOT) Study; and (6) Multi-State TB Outbreak Associated with Bone Allograft Surgery. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–24321 Filed 11–5–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0098]

Advisory Committee on Immunization Practices (ACIP); Amended Notice of Meeting

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

DATES: The meeting will be held on October 20–21, 2021, from 10:00 a.m. to 5:00 p.m., EDT (times subject to change). The docket is currently open to receive written comments. Written comments must be received on or before October 21, 2021.

SUPPLEMENTARY INFORMATION: Notice is hereby given of a change in the meeting of the Advisory Committee on Immunization Practices (ACIP); October 20, 2021, 10:00 a.m.–5:00 p.m., EDT, and October 21, 2021, 10:00 a.m.–5:00 p.m., EDT (times subject to change), in the original FRN.

The virtual meeting was published in the **Federal Register** on Wednesday, September 22, 2021, Volume 86, Number 181, pages 52683–52684.

The virtual meeting is being amended to change the date the docket was opened to receive written public comments, and updates to the Matters To Be Considered and Written Public Comment sections of the notice and should read as follows:

DATES: The meeting will be held on October 20–21, 2021, from 10:00 a.m. to 5:00 p.m., EDT (times subject to change). The public may submit written comments from October 7, 2021 through October 21, 2021.

Matters To Be Considered: The agenda will include discussions on herpes zoster vaccines, influenza vaccines, pneumococcal vaccine, and COVID–19 vaccines. Recommendation votes on herpes zoster vaccine, pneumococcal vaccine, and COVID–19 vaccines are scheduled. No Vaccines for Children (VFC) votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Written Public Comment: The docket will be opened to receive written comments on October 7, 2021. Written comments must be received on or before October 21, 2021.

The virtual meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–24320 Filed 11–5–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CK–22–003, Emerging Infections Sentinel Networks (EISN) Research.

Date: January 11, 2022.

Time: 10:00 a.m.–5:00 p.m., EST.

Place: Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329–4027.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, 1600 Clifton Road NE, Mailstop US8–1, Atlanta, Georgia 30329–4027, Telephone: (404) 718–8833, Email: *GAnderson@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–24322 Filed 11–5–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10280]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 8, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of the Information Collection:* Home Health Change of Care Notice; *Use:* The purpose of the Home Health Change of Care Notice (HHCCN) is to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Home health agencies (HHAs) are required to provide written notice to Original Medicare beneficiaries under various circumstances involving the reduction or termination of items and/or services consistent with Home Health Agencies Conditions of Participation (COPs).

The home health COP requirements are set forth in § 1891 [42 U.S.C. 1395bbb] of the Social Security Act (the Act). The implementing regulations under 42 CFR 484.10(c) specify that Medicare patients receiving HHA services have rights. The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished. The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished. The HHA must advise the patient in advance of any change in the plan of care before the change is made.''

Notification is required for covered and non-covered services listed in the plan of care (POC). The beneficiary will use the information provided to decide whether or not to pursue alternative options to continue receiving the care noted on the HHCCN. *Form Number:* CMS–10280 (OMB control number: 0938–1196); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 11,157; *Total Annual Responses:* 12,385,108; *Total Annual Hours:* 824,848. (For policy questions regarding this collection contact Jennifer McCormick at 410–786–2852.)

Dated: November 3, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–24396 Filed 11–5–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Notification of Obligation Target Status for CCDF American Rescue Plan (ARP) Act Stabilization Funds (0970–0510)

AGENCY: Office of Child Care (OCC), Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Care (OCC) plans to submit a generic information collection (GenIC) request under the umbrella generic: Generic Clearance for Financial Reports used for ACF Mandatory Grant Programs (0970–0510). This request includes an information collection for Child Care and Development Fund (CCDF) state and territory grant recipients to report obligation progress of the American Rescue Plan (ARP) Act Stabilization funds.

DATES: *Comments due within 14 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above and below.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be submitted by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF programs require detailed financial information from their grantees that allows ACF to monitor various specialized cost categories within each program, to closely manage program activities, and to have sufficient financial information to enable periodic thorough and detailed audits. The Generic Clearance for Financial Reports used for ACF Mandatory Grant Programs allows ACF programs to efficiently develop and receive approval for financial reports that are tailored to specific funding recipients and the associated needs of the program. For more information about the umbrella generic, see: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202108-0970-002.*

This specific GenIC is to meet the one-time statutory financial reporting requirement established by the ARP Act (Pub. L. 117–2, Sec. 2202). The ARP Act allocated $24 billion for CCDF for lead agencies to award subgrants to child care providers in order to stabilize the child care market. The ARP Act requires lead agencies to notify the Secretary of HHS if they are unable to obligate at least 50 percent of the Stabilization funds that are available for subgrants within 9 months of enactment.

Generic clearance approval is requested to allow ACF's OCC to collect the necessary information from CCDF lead agencies by the statutory deadline of December 11, 2021.

Respondents: State and territory CCDF administrators.

ANNUAL BURDEN ESTIMATES

Title of information collection	Number of respondents	Total number of responses	Hourly burden per response	Annual hourly burden
Notification of Obligation Target Status for CCDF ARP Act Stabilization Funds	56	1	1	56

Estimated Total Annual Burden Hours: 56.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 14 days of this publication.

(Authority: Sec. 2022, Pub. L. 117–2, Sec. 2202.)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24377 Filed 11–5–21; 8:45 am]

BILLING CODE 4184–81–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcing Solicitation of Written Comments and Call for Nominations To Inform Development of the Physical Activity Guidelines Midcourse Report on Older Adults

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) seeks public input in two forms: (1) Written comments to help inform the scope and development of the Physical Activity Guidelines (PAG) Midcourse Report on older adults and (2) nominations of qualified candidates to support the development of the report through systematic review of the scientific literature related to physical activity and older adults.

DATES: Written comments and nominations will be accepted through 11:59 p.m. E.T. on December 8, 2021.

ADDRESSES: Written comments and nominations should be submitted by email to *PAGReviews@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite 420; Rockville, MD 20852; Telephone: (240) 453–8280.

SUPPLEMENTARY INFORMATION: The *Physical Activity Guidelines for Americans* (PAG) provides science-based recommendations on how physical activity can help promote health and reduce the risk of chronic disease. The PAG serves as the benchmark and primary, authoritative voice of the federal government for providing science-based guidance on physical activity, fitness, and health in the United States. The U.S. Department of Health and Human Services (HHS) released the first edition in 2008 and the second edition in 2018. In 2013, HHS released a midcourse report highlighting strategies to increase physical activity among youth. The PAG and related reports are available at *www.health.gov/paguidelines.* The Office of Disease Prevention and Health Promotion (ODPHP), in collaboration with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the President's Council on Sports, Fitness & Nutrition (PCSFN), intends to develop a midcourse report for release in 2023. A subcommittee of the PCSFN will be convened to conduct a literature review and summarize findings which will support the development of the midcourse report.

The midcourse report will further reinforce and disseminate the PAG and the importance of regular physical activity. Despite the many benefits of physical activity for older adults, only 13.9% of adults over age 65 meet the aerobic and muscle-strengthening key guidelines (2018 data from National Health Interview Survey). Therefore, the next PAG Midcourse Report will focus on how to increase physical activity levels among older adults.

Overview: The PAG Midcourse Report will use the strong science base from the PAG published in 2018, which details the amounts and types of physical activity needed for a variety of short- and long-term benefits for older adults (see *https://health.gov/PAguidelines*) and the World Health Organization review of effective interventions for older adults (see *https://ijbnpa.biomedcentral.com/articles/10.1186/s12966-021-01140-9*). This midcourse report seeks to:

1. Highlight key components of intervention strategies that have been shown to be effective in increasing physical activity levels among older adults.

2. Identify settings where physical activity messaging/encouragement would be relevant to older adults.

3. Highlight policy, systems, and environmental interventions particularly important to this population to increase physical activity.

4. Summarize effective strategies to overcome barriers and limitations to implementing the above interventions, including (where evidence is available):

a. Emphasize equity and reduce disparities in participation, including among individuals with disabilities and individuals of racial/ethnic groups.

b. Highlight strategies to bolster mental health, build resilience, or enhance social connectedness.

Written comments: Based on the above outline, HHS requests input on how this midcourse report can best support decision makers, health professionals, educators, and others working to promote or implement physical activity among older adults in a variety of settings. For example, (1) are there other related areas this report should address that would inform and guide your work with this population? and (2) What information or knowledge gaps do you experience in your work that could be supported by a midcourse report? Comments will be accepted via email to *PAGReviews@hhs.gov* until 11:59 p.m. E.T. on December 8, 2021. HHS may contact respondents regarding their submissions to ask for clarification if needed.

Role of the Subcommittee: The subcommittee will work with a literature review team to review the evidence on effective strategies to achieve the PAG among older adults (aerobic, muscle-strengthening, balance, multicomponent). The subcommittee will be tasked to evaluate the scientific literature, grade the evidence, and summarize the science related to strategies to increase physical activity among older adults and to identify research gaps. The subcommittee will deliver its findings in a written report to the PCSFN for discussion and deliberation. The federal steering committee will use the report to inform the PAG Midcourse Report. The subcommittee is expected to be engaged throughout calendar year 2022, primarily through video and/or phone meetings.

Nominations for the Subcommittee: HHS will consider nominations, including self-nominations, for individuals qualified to carry out the above-mentioned tasks. Nominees must have an advanced degree and expertise reviewing scientific literature in the fields of physical activity, health promotion/disease prevention, gerontology/aging, public health, built environment/community design, health policy, psychology, and/or implementation science. Nominees must also currently reside in the United States. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) The name, address, daytime telephone number, and email address of the nominator and the individual being nominated; (2) a letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee that the nominee is willing to serve on a subcommittee to support development of the PAG Midcourse Report; and (3) a current copy of the nominee's curriculum vitae (CV) no more than 10 pages in length. Inclusion of the following is requested in the CV: (1) Current position, (2) current and/or past grant awards, (3) publications showing breadth and experience in areas of specialization, (4) paid and non-paid board and advisory appointments, and (5) education and occupational history.

All nominations must include the required information. Incomplete nominations will not be processed for consideration. All nomination information should be sent in a single email, with attachments, to *PAGReviews@hhs.gov.* All nominations must be submitted by 11:59 p.m. E.T. on December 8, 2021.

Equal opportunity practices regarding acceptance to this committee will be aligned with HHS policies. When possible, every effort will be made to ensure that the committee includes a diverse group of individuals with representation from various geographic locations, racial and ethnic minorities, all genders, and persons with disabilities. Individuals will be selected to represent balanced viewpoints of the scientific evidence, not to represent the viewpoints of any specific group.

Paul Reed,

Deputy Assistant Secretary for Health, RADM, U.S. Public Health Service, Office of Disease Prevention and Health Promotion.

[FR Doc. 2021–24359 Filed 11–5–21; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council on Aging.

Date: January 25–26, 2022.

Closed: January 25, 2022, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Open: January 26, 2022, 10:00 a.m. to 2:45 p.m.

Agenda: Call to order and report from the Director; Discussion of future meeting dates; Consideration of minutes of last meeting; Reports from Task Force on Minority Aging Research, Working Group on Program; Council Speaker; Program Highlights.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Closed: January 26, 2022, 2:15 p.m. to 2:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kenneth Santora, Ph.D., Director, Office of Extramural Activities, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496–9322, *ksantora@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/about/naca,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 3, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24335 Filed 11–5–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Language, Speech and Vocal Physiology.
Date: December 2, 2021.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Paul Hewett-Marx, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (240) 672–8946, *hewettmarxpn@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Endocrinology and Metabolism Topics.
Date: December 2, 2021.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Baskaran Thyagarajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (301) 867–5309, *thyagarajanb2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Endocrinology and Metabolism.
Date: December 3, 2021.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jonathan Michael Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *jonathan.peterson@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Vaccine Development and Vector Biology.
Date: December 8, 2021.
Time: 1:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–9448, *shinako.takada@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 3, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24337 Filed 11–5–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Literature Selection Technical Review Committee. The meeting is devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine and will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.
Date: February 24–25, 2022.
Time: 9:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.
Place: Virtual Meeting.
Contact Person: Dianne Babski, Associate Director, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Building 38, Room 2W04A, Bethesda, MD 20894, 301–827–4729, *babskid@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: November 3, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24336 Filed 11–5–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services announces a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC). The ISMICC is open to the public and can be accessed via telephone or webcast only, and not in person. Agenda with call-in information will be posted on SAMHSA's website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will provide information on federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED).

DATES: December 16, 2021, 1:00 p.m.–4:00 p.m. (EDT)/Open.

ADDRESSES: The meeting will be held virtually and can be accessed via Zoom.

FOR FURTHER INFORMATION CONTACT: Pamela Foote, ISMICC Designated Federal Officer, SAMHSA, 5600 Fishers Lane, 14E53C, Rockville, MD 20857; telephone: 240–276–1279; email: *pamela.foote@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in SMI and SED, research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMIs, SEDs, and advances in access to services and supports for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to SMI and SED have on public health, including public health outcomes such as: (A) Rates of suicide, suicide attempts, incidence and prevalence of SMIs, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room

boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment; (B) increased rates of employment and enrollment in educational and vocational programs; (C) quality of mental and substance use disorders treatment services; or (D) any other criteria determined by the Secretary. Finally, the ISMICC will make specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with SMI or children with SED. Not later than one (1) year after the date of enactment of the 21st Century Cures Act, and five (5) years after such date of enactment, the ISMICC shall submit a report to Congress and any other relevant federal department or agency.

II. Membership

This ISMICC consists of federal members listed below or their designees, and non-federal public members.

Federal Membership: Members include, The Secretary of Health and Human Services; The Assistant Secretary for Mental Health and Substance Use; The Attorney General; The Secretary of the Department of Veterans Affairs; The Secretary of the Department of Defense; The Secretary of the Department of Housing and Urban Development; The Secretary of the Department of Education; The Secretary of the Department of Labor; The Administrator of the Centers for Medicare and Medicaid Services; and The Commissioner of the Social Security Administration.

Non-federal Membership: Members include, 14 non-federal public members appointed by the Secretary, representing psychologists, psychiatrists, social workers, peer support specialists, and other providers, patients, family of patients, law enforcement, the judiciary, and leading research, advocacy, or service organizations.

The ISMICC is required to meet at least twice per year.

To attend virtually, submit written or brief oral comments, or request special accommodation for persons with disabilities, contact Pamela Foote. Individuals can also register on-line at: *https://snacregister.samhsa.gov/MeetingList.aspx.*

The public comment section will be scheduled at the conclusion of the meeting. Individuals interested in submitting a comment, must notify Pamela Foote on or before December 6, 2021 via email to: *Pamela.Foote@samhsa.hhs.gov.*

Up to three minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record of the meeting.

Substantive meeting information and a roster of Committee members is available at the Committee's website: *https://www.samhsa.gov/about-us/advisory-councils/meetings.*

Dated: November 2, 2021.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2021–24331 Filed 11–5–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6270–N–04]

Manufactured Housing Consensus Committee (MHCC): Notice Inviting Nominations of Individuals To Serve on the Committee

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

ACTION: Notice of request for nominations to serve on the Manufactured Housing Consensus Committee.

SUMMARY: The Department of Housing and Urban Development invites the public to nominate individuals for appointment, with the approval of the Secretary, to the Manufactured Housing Consensus Committee (MHCC), a federal advisory committee established by the National Manufactured Housing Construction and Safety Standards Act of 1974, as amended by the Manufactured Housing Improvement Act of 2000. The Department will make appointments from nominations submitted in response to this Notice. Also, individuals that applied earlier this calendar year do not need to re-apply; pursuant to this notice those applications are on file and may be considered for future appointments.

DATES: The Department will accept nominations until December 8, 2021.

ADDRESSES: Nominations must be submitted through the following website: *http://mhcc.homeinnovation.com/Application.aspx.* The submitted nominations are addressed to: Teresa B. Payne, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, c/o Home Innovation Research Labs; Attention: Kevin Kauffman, 400 Prince Georges Blvd., Upper Marlboro, MD 20774.

FOR FURTHER INFORMATION CONTACT: Teresa B. Payne, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 7th Street SW, Room 9166, Washington, DC 20410–8000; telephone number 202–402–2698 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 604 of the Manufactured Housing Improvement Act of 2000 (Pub. L. 106–569) amended the National Manufactured Housing Construction and Safety Standards Act of 1974 (42 U.S.C. 5401–5426) (Act) to require the establishment of the Manufactured Housing Consensus Committee (MHCC), a federal advisory committee, to: (1) Provide periodic recommendations to the Secretary to adopt, revise, and interpret the manufactured housing construction and safety standards; and (2) provide periodic recommendations to the Secretary to adopt, revise, and interpret the procedural and enforcement manufactured housing regulations. The Act authorizes the Secretary to appoint a total of twenty-two members to the MHCC. Twenty-one members have voting rights; the twenty-second member represents the Secretary and is a non-voting position. Service on the MHCC is voluntary. Travel and per diem for meetings is provided in accordance with federal travel policy pursuant to 5 U.S.C. 5703.

HUD seeks highly qualified and motivated individuals who meet the requirements set forth in the Act to serve as voting members of the MHCC for up to two terms of three years. The MHCC expects to meet at least one to two times annually. Meetings may take place by conference call or in person. Members of the MHCC undertake additional work commitments on subcommittees and task forces regarding issues under deliberation.

Nominee Selection and Appointment

Members of the Consensus Committee are appointed to serve in one of three member categories. Nominees will be appointed to fill voting member vacancies in the following categories:

1. *Producers*—Seven producers or retailers of manufactured housing.

2. *Users*—Seven persons representing consumer interests, such as consumer organizations, recognized consumer leaders, and owners who are residents of manufactured homes.

3. *General Interest and Public Officials*—Seven general interest and public official members.

The Act provides that the Secretary shall ensure that all interests directly

and materially affected by the work of the MHCC have the opportunity for fair and equitable participation without dominance by any single interest; and may reject the appointment of any one or more individuals in order to ensure that there is not dominance by any single interest. For purposes of this determination, dominance is defined as a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation.

Additional requirements governing appointment and member service include:

(1) Nominees appointed to the User category, and three of the individuals appointed to the General Interest and Public Official category shall not have a significant financial interest in any segment of the manufactured housing industry; or a significant relationship to any person engaged in the manufactured housing industry.

(2) Each member serving in the User category shall be subject to a ban disallowing compensation from the manufactured housing industry during the period of, and during the one year following, his or her membership on the MHCC.

(3) Nominees selected for appointment to the MHCC shall be required to provide disclosures and certifications regarding conflict-of-interest and eligibility for membership prior to finalizing an appointment.

All selected nominees will be required to submit certifications of eligibility under the foregoing criteria as a prerequisite to final appointment.

Consensus Committee—Advisory Role

The MHCC's role is to solely advise the Secretary on the subject matter described above.

Federal Advisory Committee Act

The MHCC is subject to the requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix), 41 CFR parts 101–6 and 102–3 (the FACA Final Rule), and to the Presidential Memorandum, dated June 18, 2010, directing all heads of executive departments and agencies not to make any new appointments or reappointments of federally registered lobbyists to advisory committees and other boards and commissions. The June 18, 2010, Presidential Memorandum authorized the Director of the Office of Management and Budget (OMB) to issue guidance to implement this policy. On August 13, 2014 (79 FR 47482), OMB issued guidance regarding the prohibition against appointing or re-appointing federally registered lobbyists to clarify that the ban applies to persons serving on advisory committees, boards, and commissions in their individual capacity and does not apply if they are specifically appointed to represent the interests of a nongovernmental entity, a recognizable group of persons or nongovernmental entities (an industry sector, labor unions, environmental groups, etc.), or state or local governments.

Term of Office

Consensus Committee members serve at the discretion of the Secretary or for a three-year term and for up to two terms.

Nominee Information

Individuals seeking nomination to the MHCC should submit detailed information documenting their qualifications as addressed in the Act and this Notice. Individuals may nominate themselves. HUD recommends that the application form be accompanied by a resume.

Additional Information

The Department will make appointments from nominations submitted in response to this Notice. Also, individuals that applied earlier this calendar year do not need to re-apply; pursuant to this notice those applications are on file and may be considered for future appointments.

To be considered for appointment to a position of an MHCC member whose term expires in December of 2021 or to fill any MHCC vacancy that currently exists, the nomination should be submitted by December 8, 2021. Appointments will be made at the discretion of the Secretary.

Janet Golrick,

Acting Chief of Staff, Office of Housing—Federal Housing Administration.

[FR Doc. 2021–24333 Filed 11–5–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6297–N–01]

Notice of HUD Vacant Loan Sales (HVLS 2022–1)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice of sales of reverse mortgage loans.

SUMMARY: This notice announces HUD's intention to competitively offer multiple residential reverse mortgage pools, including six multi-loan pools and one single asset pool, consisting of approximately 1,700 reverse mortgage notes secured by vacant properties with a loan balance of approximately $420 million. The Secretary will prioritize bids on some of these assets to qualified non-profit or unit of state or local government bidders. This notice also generally describes the bidding process for the sale and certain persons who are ineligible to bid. This is the seventh sale offering of its type and the sale will be held on December 1, 2021.

DATES: For this sale action, the Bidder's Information Package (BIP) was made available to qualified bidders on October 21, 2021. Bids for the HVLS 2022–1 sale will be accepted on the Bid Date of December 1, 2021 (Bid Date). HUD anticipates that award(s) will be made on or about December 3, 2021 (the Award Date).

ADDRESSES: To become a qualified bidder and receive the BIP, prospective bidders must complete, execute, and submit a Confidentiality Agreement and a Qualification Statement acceptable to HUD. Both documents are available in the announcement posted on the HUD website: *https://www.hud.gov/program_offices/housing/comp/asset/hsgloan* or on the Program Financial Advisor (PFA), Falcon Capital Advisors, website: *http://www.falconassetsales.com.*

Due to remote work processes during the COVID–19 National Emergency and limited access to standard mail, electronic submission of executed documents via email at *HUDsales@FalconAssetSales.com* is preferred. Prospective bidders may utilize digital signatures on the electronically submitted documents. If you do not submit electronically, please submit executed documents via mail or facsimile to Falcon Capital Advisors: Falcon Capital Advisors, 427 N Lee Street, Alexandria, VA 22314, Attention: Dan Wentworth, HUD HVLS Loan Sale Coordinator. eFax: 1–202–393–4125.

FOR FURTHER INFORMATION CONTACT: John Lucey, Director, Office of Asset Sales, Room 3136, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410–8000; telephone 202–708–2625, extension 3927 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: This notice announces HUD's intention to sell in HVLS 2022–1 due and payable Secretary-held reverse mortgage loans.

HUD is offering six multiple residential reverse mortgage pools totaling approximately 1,700 reverse mortgage notes with a loan balance of approximately $420 million. The mortgage loans consist of first liens secured by single family, vacant residential properties, where all borrowers are deceased, and no borrower is survived by a non-borrowing spouse. Qualified non-profit or unit of state or local government bidders will have the opportunity to bid on all loans and may receive a priority bidding opportunity for up to 50 percent of the loans in five of the multi-loan pools (Carve-Out Pool).

HUD also intends to include in HVLS 2022–1 a single asset pool for sale consisting of a reverse mortgage loan secured by an Illinois multi-unit single-family property, where there is no surviving borrower or non-borrowing spouse but some units are currently tenant-occupied. This single asset pool has a loan balance of approximately $158 thousand. For one of the multi-loan pools and the single asset pool, HUD will prioritize bids from non-profit or unit of state or local government bidders (each a Priority Pool).

A listing of the mortgage loans will be included in the due diligence materials made available to qualified bidders. The mortgage loans will be sold without FHA insurance and with servicing released. HUD will offer qualified bidders an opportunity to bid competitively on the mortgage loan pools.

The Bidding Process

The BIP describes in detail the procedure for bidding in HVLS 2022–1. The BIP also includes a standardized non-negotiable Conveyance, Assignment and Assumption Agreement for HVLS 2022–1 (CAA). Qualified bidders will be required to submit a deposit with their bid. Deposits are calculated based upon each qualified bidder's aggregate bid price.

HUD will evaluate the bids submitted and determine the successful bid, in terms of the best value to HUD, in its sole and absolute discretion. If a qualified bidder is successful, the qualified bidder's deposit will be non-refundable and will be applied toward the purchase price. Deposits will be returned to unsuccessful bidders.

This notice provides some of the basic terms of sale. The CAA, which is included in the BIP, provides comprehensive contractual terms and conditions. To ensure a competitive bidding process, the terms of the bidding process and the CAA are not subject to negotiation.

Due Diligence Review

The BIP describes how qualified bidders may access the due diligence materials remotely via a high-speed internet connection.

Mortgage Loan Sale Policy

HUD reserves the right to remove mortgage loans from HVLS 2022–1 at any time prior to the Award Date and the settlement date for the mortgage loans. HUD also reserves the right to reject any and all bids, in whole or in part, and include any reverse mortgage loans in a later sale. Deliveries of mortgage loans will occur in conjunction with settlement and servicing transfer no later than 60 days after the Award Date.

The HVLS 2022–1 reverse mortgage loans were insured by and were assigned to HUD pursuant to section 255 of the National Housing Act, as amended. The sale of the reverse mortgage loans is pursuant to section 204(g) of the National Housing Act.

Mortgage Loan Sale Procedure

HUD selected an open competitive whole-loan sale as the method to sell the mortgage loans for this specific sale transaction. For HVLS 2022–1, HUD has determined that this method of sale optimizes HUD's return on the sale of these loans, affords the greatest opportunity for all qualified bidders to bid on the mortgage loans, and provides the quickest and most efficient vehicle for HUD to dispose of the due and payable mortgage loans.

Bidder Ineligibility

In order to bid in HVLS 2022–1 as a qualified bidder, a prospective bidder must complete, execute, and submit both a Confidentiality Agreement and a Qualification Statement acceptable to HUD. In the Qualification Statement, the prospective bidder must provide certain representations and warranties regarding the prospective bidder, including but not limited to (i) the prospective bidder's board of directors, (ii) the prospective bidder's direct parent, (iii) the prospective bidder's subsidiaries, (iv) any related entity with which the prospective bidder shares a common officer, director, subcontractor or sub-contractor who has access to Confidential Information as defined in the Confidentiality Agreement or is involved in the formation of a bid transaction (collectively the ''Related Entities''), and (v) the prospective bidder's repurchase lenders. The prospective bidder is ineligible to bid on any of the reverse mortgage loans included in HVLS 2022–1 if the prospective bidder, its Related Entities, or its repurchase lenders, are any of the following, unless other exceptions apply as provided for in the Qualification Statement.

1. An individual or entity that is currently debarred, suspended, or excluded from doing business with HUD pursuant to the Governmentwide Suspension and Debarment regulations at 2 CFR parts 180 and 2424;

2. An individual or entity that is currently suspended, debarred, or otherwise restricted by any department or agency of the federal government or of a state government from doing business with such department or agency;

3. An individual or entity that is currently debarred, suspended, or excluded from doing mortgage related business, including having a business license suspended, surrendered or revoked, by any federal, state, or local government agency, division, or department;

4. An entity that has had its right to act as a Government National Mortgage Association (''Ginnie Mae'') issuer terminated and its interest in mortgages backing Ginnie Mae mortgage-backed securities extinguished by Ginnie Mae;

5. An individual or entity that is in violation of its neighborhood stabilizing outcome obligations or post-sale reporting requirements under a Conveyance, Assignment and Assumption Agreement executed for any previous mortgage loan sale of HUD;

6. An employee of HUD's Office of Housing, a member of such employee's household, or an entity owned or controlled by any such employee or member of such an employee's household with household to be inclusive of the employee's father, mother, stepfather, stepmother, brother, sister, stepbrother, stepsister, son, daughter, stepson, stepdaughter, grandparent, grandson, granddaughter, father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, first cousin, the spouse of any of the foregoing, and the employee's spouse;

7. A contractor, subcontractor, and/or consultant or advisor (including any agent, employee, partner, director, or principal of any of the foregoing) who performed services for or on behalf of HUD in connection with the sale;

8. An individual or entity that knowingly acquired or will acquire prior to the sale date material non-public information, other than that information which is made available to Bidder by HUD pursuant to the terms of this Qualification Statement, about mortgage loans offered in the sale;

9. An individual or entity which knowingly employs or uses the services of an employee of HUD's Office of Housing (other than in such employee's official capacity); or

10. An individual or entity that knowingly uses the services, directly or indirectly, of any person or entity ineligible under 1 through 10 to assist in preparing any of its bids on the mortgage loans.

The Qualification Statement has additional representations and warranties which the prospective bidder must make, including but not limited to the representation and warranty that the prospective bidder or its Related Entities are not and will not knowingly use the services, directly or indirectly, of any person or entity that is, any of the following (and to the extent that any such individual or entity would prevent the prospective bidder from making the following representations, such individual or entity has been removed from participation in all activities related to this sale and has no ability to influence or control individuals involved in formation of a bid for this sale):

(1) An entity or individual is ineligible to bid on any included reverse mortgage loan or on the pool containing such reverse mortgage loan because it is an entity or individual that:

(a) Serviced or held such reverse mortgage loan at any time during the six-month period prior to the bid, or

(b) Is any principal of any entity or individual described in the preceding sentence;

(c) Any employee or subcontractor of such entity or individual during that six-month period; or

(d) Any entity or individual that employs or uses the services of any other entity or individual described in this paragraph in preparing its bid on such reverse mortgage loan.

Freedom of Information Act Requests

HUD reserves the right, in its sole and absolute discretion, to disclose information regarding HVLS 2022–1, including, but not limited to, the identity of any successful qualified bidder and its bid price or bid percentage for any pool of loans or individual loan, upon the closing of the sale of all the mortgage loans. Even if HUD elects not to publicly disclose any information relating to HVLS 2022–1, HUD will disclose any information that HUD is obligated to disclose pursuant to the Freedom of Information Act and all regulations promulgated thereunder.

Scope of Notice

This notice applies to HVLS 2022–1 and does not establish HUD's policy for the sale of other mortgage loans.

Janet Golrick,

Acting, Chief of Staff, Office of Housing—Federal Housing Administration.

[FR Doc. 2021–24294 Filed 11–5–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2021–N187; FXES11130600000]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for Desert Yellowhead

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability for review and comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of a draft recovery plan for desert yellowhead, a plant listed as threatened under the Endangered Species Act. We request review and comment on this draft recovery plan from Federal, State, Tribal, and local agencies and the public.

DATES: We must receive any comments on the draft recovery plan on or before January 7, 2022.

ADDRESSES:

Document availability: Copies of the draft recovery plan are available at *http://www.fws.gov/endangered/species/recovery-plans.html* and at *https://ecos.fws.gov/ecp/species/7754.* Alternatively, you may request a copy by U.S. mail from the Wyoming Field Office; 334 Parsley Blvd., Cheyenne, WY 82007; or by telephone at 307–772–2374. Persons who use a telecommunications device for the deaf may call the Federal Relay Service at 800–877–8339.

Submitting comments: If you wish to comment on the draft recovery plan, you may submit your comments in writing by email to Tyler Abbott, at *tyler_abbott@fws.gov,* or by U.S. mail to Tyler Abbott, Wyoming Field Supervisor, at the above U.S. mail address.

FOR FURTHER INFORMATION CONTACT: Tyler Abbott, Wyoming Field Supervisor, at the above U.S. mail address or by telephone at 307–772–2374. Persons who use a telecommunications device for the deaf may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft recovery plan for desert yellowhead (*Yermo xanthocephalus*), a plant listed as threatened under the Endangered Species Act, as amended (Act; 16 U.S.C. 1531 *et seq.*). The draft recovery plan includes objective, measurable criteria, and site-specific management actions as may be necessary to remove the species from the Federal List of Endangered and Threatened Plants. We request review and comment on this draft recovery plan from Federal, State, Tribal, and local agencies and the public.

Species Information

On April 15, 2002, we listed desert yellowhead as a threatened plant (March 14, 2002; 67 FR 11442). On April 15, 2004, we designated approximately 360 acres (ac) (146 hectares (ha)) of critical habitat (March 16, 2004; 69 FR 12278).

Desert yellowhead is the only member of a monotypic genus. It is an endemic, herbaceous, perennial plant, with two known populations in Fremont County, Wyoming—Sand Draw and Cedar Rim. The two populations are approximately 5 miles (mi) (8 kilometers (km)) apart. New plants establish from seed or ramet, grow for multiple years before flowering, and may subsequently have years in which no flower production occurs (Doak *et al.* 2016, p. 4). This species is likely pollinated by visually oriented insects attracted to its bright yellow disk flowers and bracts (Dorn 1991, pp. 198–201). The two populations are found in sparsely vegetated cover at approximately 6,750 feet (ft) (2,057 meters (m)) for Sand Draw and 7,080 ft (2,158 m) for Cedar Rim.

We do not know the historical distribution of desert yellowhead. Currently, the total area occupied by the two populations is approximately 11.9 ac (4.8 ha). Both populations are located on lands administered by the Bureau of Land Management (BLM). Only the Sand Draw population occurs within designated critical habitat; the Cedar Rim population was not discovered until 2010, after critical habitat had been designated. Due to the variability of monitoring methods employed in different years, it is difficult to evaluate abundance trends; however, populations appear relatively stable.

The primary threat to desert yellowhead identified at the time of listing was mineral development, and secondary threats included invasive plants; grazing and trampling by livestock, wild horses, and ungulates; off-road vehicle recreation; deliberate

damage or destruction of plants; and wildfire. Currently, the primary threat to the species is exploration for and development of locatable mineral resources, such as opals, gold, uranium, and zeolites. Without additional protections, we anticipate an increase in the magnitude of this threat affecting the species' future resiliency, redundancy, and representation. Secondary threats continue to include potential invasive plant encroachment; grazing and trampling by livestock, wild horses, and ungulates; off-road vehicle recreation; deliberate damage or destruction of plants; and potential wildfire. The potential threats from invasive plants and wildfire could be exacerbated by climate change.

Several regulatory mechanisms have been initiated since listing in 2002 as follows:

(1) Desert yellowhead is designated a sensitive species under the BLM's 6840 Manual (BLM 2008, entire) and under BLM's current Lander Resource Management Plan (RMP) (BLM 2014, entire). We expect the current Lander RMP to remain in place for another 15–20 years, and that a renewed RMP would continue to offer protections to this species, regardless of its status as a federally listed species.

(2) On July 12, 2005, the BLM published a notice in the **Federal Register** announcing the closure of certain BLM-administered public lands to all types of motor vehicle use to protect desert yellowhead and its critical habitat (70 FR 40053). The closure affects public lands located within, and adjacent to, the 360-ac (146-ha) designated critical habitat of the Sand Draw population of desert yellowhead.

(3) On January 30, 2008, Public Land Order number 7688 provided for the withdrawal of public lands for the protection of desert yellowhead (FR 73 5586). The order withdrew the 360 ac (146 ha) of land identified as critical habitat surrounding the Sand Draw population from surface entry and mining for 20 years. This protection is due for renewal in 2028. The Cedar Rim population was not known at this time, and discussions regarding the establishment of a mineral withdrawal for this population are ongoing.

Recovery Planning Process

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the Service's endangered species program. Recovery means improving the status of a listed species to the point at which listing is no longer necessary according to the criteria specified under section 4(a)(1) of the Act. The Act requires recovery plans for listed species unless such a plan would not promote the conservation of a particular species. To help guide recovery efforts, we prepare recovery plans to promote the conservation of the species.

The purpose of a recovery plan is to provide a recommended framework for the recovery of a species so that protection of the Act is no longer necessary. Pursuant to section 4(f) of the Act, a recovery plan must, to the maximum extent possible, include:

(1) A description of site-specific management actions as may be necessary to achieve the plan's goal for the conservation and survival of the species;

(2) Objective, measurable criteria which, when met, would support a determination under section 4(a)(1) of the Act that the species should be removed from the List of Endangered and Threatened Plants; and

(3) Estimates of time and costs required to carry out those measures needed to achieve the plan's goal and to achieve intermediate steps toward that goal.

We used our new recovery planning and implementation (RPI) process to develop the draft recovery plan for desert yellowhead. The RPI process helps reduce the time needed to develop and implement recovery plans, increases the relevancy of the recovery plan over longer timeframes, and adds flexibility so that the recovery plan can be more easily adjusted to new information and circumstances. Under our RPI process, a recovery plan will include the three statutorily required elements for recovery plans—objective and measurable criteria, site-specific management actions, and estimates of time and cost—along with a concise introduction and our strategy for how we plan to achieve species recovery. The RPI recovery plan is supported by a separate SSA report for the desert yellowhead (Service 2019, entire). The SSA is an in-depth, but not exhaustive, review of the species' biology and threats, an evaluation of its biological status, and an assessment of the resources and conditions needed to maintain long-term viability. The SSA provides the scientific background and threats assessment for desert yellowhead, which are key to the development of the recovery plan. A third, separate working document, called the recovery implementation strategy (RIS), steps down the more general descriptions of actions in the recovery plan to detail the specifics needed to implement the recovery plan, which improves the flexibility of the recovery plan. The RIS will be adaptable, with new information on actions incorporated, as needed, without requiring a concurrent revision to the recovery plan, unless changes to the three statutory elements are required.

Draft Recovery Plan

Below, we summarize components from our draft recovery plan. Please reference the draft recovery plan for full details (see **ADDRESSES**).

The draft recovery plan describes recovery as the maintenance of two (redundant) stable (resilient) populations within the species' historical range (representation), with conservation measures in place to reduce key threats.

The draft recovery plan includes recovery criteria for delisting that when met would indicate that the desert yellowhead may no longer need the protections of the Act. Delisting criteria include:

(1) Long term, renewable protections from mineral resource extraction are in place for both the Sand Draw and Cedar Rim populations and will remain in place for at least 10 years following delisting.

(2) The Sand Draw and Cedar Rim populations are secure, as evidenced by a stable or increasing population trend, with more than 5,797 individuals counted in Sand Draw's monitored quadrats and more than 242 individuals counted in Cedar Rim's monitored transects for 8 out of 10 consecutive survey years.

(3) Both the Sand Draw and Cedar Rim populations show evidence of sexual reproduction as evidenced by the production of at least one seed with a mature embryo in both populations over a 10-year period.

(4) A banked seed source containing seeds from both populations of desert yellowhead is secured in a Center for Plant Conservation (CPC)-affiliated institution.

To help meet these criteria, the draft recovery plan identifies recovery actions for each criterion.

Peer Review

In accordance with our July 1, 1994, peer review policy (59 FR 34270; July 1, 1994); our August 22, 2016, Director's Memo on the Peer Review Process; and the Office of Management and Budget's December 16, 2004, Final Information Quality Bulletin for Peer Review (revised June 2012), we solicited independent scientific reviews of the information contained in the SSA

report. Results of this structured peer review process can be found at *https://www.fws.gov/mountain-prairie/science/peerReview.php.* We also submitted our SSA report to our Federal and State partners for their scientific review. There is no overlap of occupied habitat or critical habitat with Tribal lands. We incorporated the results of the peer and partner review in the SSA report, as appropriate. The SSA report is the scientific foundation for the draft recovery plan.

Request for Public Comments

This notice opens the public review and comment period for our draft recovery plan for the desert yellowhead. Section 4(f) of the Act requires that we provide public notice and an opportunity for public review and comment during the development of recovery plans. All comments we receive by the date specified (see **DATES**) will be considered prior to approval of the recovery plan. Written comments and materials regarding the recovery plan should be sent via one of the means in the **ADDRESSES** section.

We will consider all information we receive during the public comment period, and particularly look for comments that provide scientific rationale or factual background. The Service and other Federal agencies and partners will take these comments into consideration in the course of implementing an approved final recovery plan. We are specifically seeking comments and suggestions on the following questions:

- Understanding that the time and cost presented in the draft recovery plan will be fine-tuned when localized recovery implementation strategies are developed, do you think that the estimated time and cost to recovery are realistic? Is the estimate reflective of the time and cost of actions that may have already been implemented by Federal, State, county, or other agencies? Please provide suggestions or methods for determining a more accurate estimation.
- Do the draft recovery criteria provide clear direction to partners on what is needed to recover desert yellowhead? How could they be improved for clarity?
- Are the draft recovery criteria both objective and measurable given the information available for desert yellowhead now and into the future? Please provide suggestions.
- Do you think that the draft recovery actions presented in the draft recovery plan generally cover the types of actions necessary to meet the recovery criteria? If not, what general actions are missing? Are any of the draft recovery actions unnecessary for achieving recovery? Have we prioritized the actions appropriately?

Public Availability of Comments

We will summarize and respond to the issues raised by the public in an appendix to the approved final recovery plan. 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. You may request at the top of your comment that we withhold this information from public review; however, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Anna Muñoz,

Acting Deputy Regional Director.

[FR Doc. 2021–24392 Filed 11–5–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2021–0123; FXES11130400000EA–123–FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Sand Skink, Lake County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from Pulte Home Company, LLC—North Florida Division (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed sand skink incidental to construction in Lake County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

DATES: We must receive your written comments on or before December 8, 2021.

ADDRESSES:

Obtaining Documents: You may obtain copies of the documents online in Docket No. FWS–R4–ES–2021–0123 at *http://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by any of the following methods:

- *Online: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2021–0123.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2021–0123; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Erin M. Gawera, by telephone at (904) 731–3121 or via email at *erin_gawera@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from Pulte Home Company, LLC—North Florida Division (Chicone) 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*) incidental to the construction of a residential development (project) in Lake 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 this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231 *et seq.*). To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

Project

The applicant requests a 5-year ITP to take sand skinks through the conversion of approximately 2.70 acres (ac) of occupied sand skink foraging and sheltering habitat incidental to the construction of a residential development located on a 254.87-ac parcel in Section 24, Township 23 South, Range 26 East, Lake County, Florida, identified by Parcel ID numbers 24–23–26–0001–0000–0100, 24–23–26–0002–0000–0600, 24–23–26–0002–0000–1200 and 24–23–26–0001–0000–

0400. The applicant proposes to mitigate for take of the sand skinks by the purchase the credits equivalent to 5.40 ac of skink-occupied habitat from Lake Wales Ridge Conservation Bank or another Service-approved Conservation Bank. The Service would require the applicant to purchase the credits prior to any clearing activities.

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.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including land clearing, infrastructure building, landscaping, and the proposed mitigation measures, would individually and cumulatively have a minor or negligible effect on sand skinks and the environment. Therefore, we have preliminarily concluded that the ITP for this project would qualify for categorical exclusion and the HCP is low effect under our NEPA regulations at 43 CFR 46.205 and 46.210. A low-effect HCP is one that would result in (1) minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) minor or negligible effects on other environmental values or resources; and (3) impacts that, when considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not over time result in significant cumulative effects to environmental values or resources.

Next Steps

The Service will evaluate the application and the comments received 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 above findings, 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 PER0017031–0 to Pulte Home Company, LLC—North Florida Division.

Authority

The Service provides this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

Robert L. Carey,

Division Manager, Environmental Review, Florida Ecological Service Field Office.

[FR Doc. 2021–24356 Filed 11–5–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–ES–2021–N194; FXES11130500000–201–FF05E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Reviews of Eight Northeastern Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are initiating 5-year reviews under the Endangered Species Act, as amended, for eight northeastern species. A 5-year review is based on the best scientific and commercial data available at the time of the review. We are requesting submission of any such information that has become available since the previous 5-year review for each species.

DATES: To ensure consideration, please submit your written information by December 8, 2021. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how and where to submit information, see Request for New Information and Table 2—Contacts under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: *General Information:* Martin Miller, via email at *martin_miller@fws.gov,* and via U.S. mail at U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035.

Species-Specific Information and Submission of Comments: Contact the appropriate person or office listed in Table 2—Contacts in **SUPPLEMENTARY INFORMATION**.

Individuals who are deaf or hard of hearing may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, are initiating 5-year reviews under the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) for eight northeastern species: The endangered Shenandoah salamander (*Plethodon shenandoah*), rough rabbitsfoot (*Quadrula cylindrica strigillata*), Roanoke logperch (*Percina rex*), and Harperella (*Ptilimnium nodosum*) and the threatened Madison Cave isopod (*Antrolana lira*), small whorled pogonia (*Isotria medeoloides*), sensitive joint-vetch (*Aeschynomene virginica*), and Cheat Mountain salamander (*Plethodon nettingi*).

A 5-year review is based on the best scientific and commercial data available at the time of the review. We are requesting submission of any such information that has become available since the most recent status review for each species.

Why do we conduct 5-year reviews and species status assessments?

Under the ESA, we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in title 50 of the Code of Federal Regulations at 50 CFR 17.11(h) (for wildlife) and 50 CFR 17.12(h) (for plants). Listed wildlife and plants can also be found at *http://ecos.fws.gov/tess_public/pub/listedAnimals.jsp* and *http://ecos.fws.gov/tess_public/pub/listedPlants.jsp,* respectively. Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species under active review. For additional information about 5-year reviews, refer to our fact sheet at *http://www.fws.gov/endangered/what-we-do/recovery-overview.html.*

What species are under review?

We are initiating 5-year status reviews of the species in table 1.

TABLE 1—SPECIES UNDER REVIEW

Common name	Scientific name	Status	Where listed	Listing date and citation
Shenandoah salamander	*Plethodon shenandoah*	Endangered	Wherever found	08/18/1989, 54 FR 34464.

TABLE 1—SPECIES UNDER REVIEW—Continued

Common name	Scientific name	Status	Where listed	Listing date and citation
Rough rabbitsfoot	*Quadrula cylindrica strigillata.*	Endangered	Wherever found	01/10/1997, 62 FR 1647.
Roanoke logperch	*Percina rex*	Endangered	Wherever found	08/18/1989, 54 FR 34468.
Harperella	*Ptilimnium nodosum*	Endangered	Wherever found	09/28/1988, 53 FR 37978.
Madison Cave isopod	*Antrolana lira*	Threatened	Wherever found	10/04/1982, 47 FR 43699.
Small whorled pogonia	*Isotria medeoloides*	Threatened	Wherever found	09/09/1982, 47 FR 39827; 10/06/1994, 59 FR 50852.
Sensitive joint-vetch	*Aeschynomene virginica*	Threatened	Wherever found	05/20/1992, 57 FR 21569.
Cheat Mountain salamander.	*Plethodon nettingi*	Threatened	Wherever found	08/18/1989, 54 FR 34464.

What information do we consider in our 5-year reviews and species status assessments?

A 5-year review considers all new information available at the time of the review. In conducting the review, we consider the best scientific and commercial data that have become available since the most recent status review. We are seeking new information specifically regarding:

(1) Species biology, including, but not limited to, life-history and habitat requirements and impact tolerance thresholds;

(2) Historical and current population conditions, including, but not limited to, population abundance, trends, distribution, demographics, and genetics;

(3) Historical and current habitat conditions, including, but not limited to, amount, distribution, and suitability;

(4) Historical and current threats, threat trends, and threat projections in relation to the five listing factors (as defined in section 4(a)(1) of the ESA);

(5) Conservation measures for the species that have been implemented or are planned; and

(6) Other new information, data, or corrections, including, but not limited to, taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information received will be considered during the 5-year review and will also be useful in evaluating ongoing recovery programs for the species.

Request for New Information

To ensure that 5-year reviews are based on the best available scientific and commercial information, we request new information from all sources. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

How do I ask questions or provide information?

Please submit your questions, comments, and materials to the appropriate contact in table 2, below. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

Public Availability of Comments

Before including your address, phone number, electronic mail address, or other personal identifying information in your submission, you should be aware that your entire submission—including your personal identifying information—may be made publicly available at any time.

Although you can request that personal information be withheld from public review, we cannot guarantee that we will be able to do so.

Contacts

New information on the species covered in this notice should be submitted by mail or electronic mail to the appropriate contact shown in table 2, by the deadline provided above in **DATES**.

TABLE 2—CONTACTS

Species	Contact person, email	Contact address
Shenandoah salamander	Jennifer Stanhope, *jennifer_stanhope@fws.gov*	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Rough rabbitsfoot	Kim Maison, *kim_maison@fws.gov*	U.S. Fish and Wildlife Service, Southwestern Virginia Field Office, 330 Cummings Street, Abingdon, VA 24210.
Roanoke logperch	Sumalee Hoskin, *sumalee_hoskin@fws.gov*	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Harperella	Jennifer L. Norris, *jennifer_l_norrris@fws.gov*	U.S. Fish and Wildlife Service, West Virginia Field Office, 6263 Appalachian Highway, Davis, WV 26260.
Madison Cave isopod	Sumalee Hoskin, *sumalee_hoskin@fws.gov*	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Small whorled pogonia	Cherry Keller, *cherry_keller@fws.gov*	U.S. Fish and Wildlife Service, Chesapeake Bay Field Office, 177 Admiral Cochrane Drive, Annapolis, MD 21401.
Sensitive joint-vetch	Jennifer Stanhope, *jennifer_stanhope@fws.gov*	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Cheat Mountain salamander	Jennifer L. Norris, *jennifer_l_norrris@fws.gov*	U.S. Fish and Wildlife Service, West Virginia Field Office, 6263 Appalachian Highway, Davis, WV 26260.

Authority

We publish this document under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Wendi Weber,

Regional Director, Northeast Region.

[FR Doc. 2021–24350 Filed 11–5–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX22WB12E6R03; OMB Control Number 1028–xxxx]

Agency Information Collection Activities; Caribou Video Data Scoring

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 7, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, email *heatherjohnson@usgs.gov,* or by telephone at 907–786–7155. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: We have developed an online application for project collaborators and volunteers to watch video clips that were collected from caribou collars (animal-borne video collars) and enter information about the behaviors and habitats observed in the clips. Information collected from the participants will be analyzed to describe caribou foraging behavior, how it varies across the summer, and the factors that influence it. This information is being collected as part of a long-term project to understand how climate variability influences caribou forage conditions, behaviors, distributions, and population dynamics. Results of the analyses will be published in peer-reviewed scientific publications that will be available to the public.

Title of Collection: Caribou Video Data Scoring.

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Project collaborators (including some DOI agency employees) and volunteers.

Total Estimated Number of Annual Responses: 5,000.

Estimated Completion Time per Response: 2 minutes on average.

Total Estimated Number of Annual Burden Hours: 166.

Respondent's Obligation: Voluntary.

Frequency of Collection: Depends on the time and interest of the respondent. Some respondents will enter information on a daily or weekly basis, others will enter information less frequently.

Total Estimated Annual Nonhour Burden Cost: None.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

John Pearce,

Associate Center Director for Ecosystems.

[FR Doc. 2021–24298 Filed 11–5–21; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032947; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Valley Authority, Knoxville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Tennessee Valley Authority (TVA) has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribe. Representatives of any Indian Tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the TVA. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes stated in this notice may proceed.

DATES: Representatives of any Indian Tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the TVA at the address in this notice by December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Thomas O. Maher, Tennessee Valley Authority, 400 West Summit Hill Drive, WT11C, Knoxville, TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C.

3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Tennessee Valley Authority, Knoxville, TN. The human remains and associated funerary objects were removed from site 40TR27, in Trousdale County, TN.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.9(e). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary objects was made by TVA's professional staff. On September 25, 2019, the TVA invited the following Indian Tribes to consult on the disposition of the human remains and associated funerary objects: The Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Coushatta Tribe of Texas [previously listed as Alabama-Coushatta Tribes of Texas]; Cherokee Nation; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Kialegee Tribal Town; Shawnee Tribe; The Muscogee (Creek) Nation; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma. On October 29, 2019, the TVA conducted a telephonic consultation with representatives of the Cherokee Nation; Eastern Band of Cherokee Indians; and The Muscogee (Creek) Nation. Hereafter, all the Indian Tribes listed in this section are referred to as ''The Consulted and Notified Tribes.''

As a result of consultation, the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation jointly requested transfer of control of the human remains and associated funerary objects. No objections to this joint transfer of control were received from The Consulted and Notified Tribes.

History and Description of the Remains

Between 1980 and 1982, human remains representing, at minimum, 74 individuals were removed from the Duncan Tract site, 40TR27, in Trousdale County, TN. This site was first recorded by Robert Jolley in January 1980, as part of a TVA survey of potential soil borrow areas near the construction site of TVA's Hartsville Nuclear Plant. Under contract with the TVA, the Anthropological Research Center of Memphis State University (now Memphis University) mitigated the adverse effects of the planned soil borrow pit on this site.

Excavations took place primarily from August to December of 1980, with follow-up excavations in 1981 and 1982. The archeological methods employed included hand excavation and mechanical stripping of the plow zone, and excavation of features penetrating the subsoil. Seven circular structures were identified from post mold patterns and 130 pits were excavated. In their summary report of the excavations submitted to the TVA in 1983, Charles McNutt and Guy Weaver believed the primary occupations at the Duncan Tract site date to the Early and Middle Woodland, but radiocarbon dates and projectile points suggest the existence of an earlier, Archaic period occupation.

Sometime after 1982, Memphis University transferred the artifacts excavated from the Duncan Tract site to the Tennessee Division of Archaeology (TDOA) in Nashville, TN. According to TDOA, the TVA transferred the collection to the Department of Anthropology at the University of Tennessee at Knoxville (UTK) sometime between 1991 and 1997. None of the original excavation forms, maps, or notes have been found at Memphis University, TDOA, or UTK. The lack of original excavation documents has complicated the identification of associated and unassociated funerary objects that were intentionally placed with human remains. While it is possible that some objects were part of the midden soil through which the burial unit was excavated, due to the lack of definitive evidence, the TVA has decided to offer for disposition those items excavated at site 40TR27 from the features that held human remains.

Although most of the human remains are fragmentary, both males and females are present. They range in age from newborn to over 50 years old. No known individuals were identified. The 4,689 associated funerary objects found in burial features include two abraders, one piece of aster, six biface or biface fragments, 832 animal bones or bone fragments, eight radiocarbon samples, 10 pieces of charcoal, two pieces of chert, three cores, 1,459 pieces of debitage, one drill, one end scraper, 24 fire-cracked rocks, six flake tools, 536 unidentified flora fragments, four fossils, one piece of groundstone, 758 carbonized hickory nuts, one chert knife, 52 pieces of limestone, one stone pestle, one pot sherd, 10 projectile points or knives, one quartzite nodule, 536 pieces of rock, 55 rocks or debitage, three pieces of sandstone, two scrapers, one piece of shale, 75 shells, 43 shell and bone fragments, 143 soil samples, one animal tooth, two unifacial tools, two utilized flakes, 63 walnut fragments, 41 walnut and hickory fragments, and two worked animal bones.

Site 40TR27 lies outside the boundary of any area recognized by a final judgment of the Indian Claims Commission or the United States Court of Claims, or a ratified treaty as the aboriginal land of an Indian Tribe. On March 14, 1775, Richard Henderson, representing the Transylvania Company, met with the Cherokee to negotiate the purchase of land including Trousdale County, TN, for the creation of a 14th colony. The Treaty of Sycamore Shoals was not acknowledged by the United States government or the governments of the states of Virginia and North Carolina. Therefore, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of an Indian Tribe or a Native Hawaiian organization, or the ''aboriginal land'' of an Indian Tribe pursuant to 43 CFR 10.11.

Pursuant to 25 U.S.C. 3006(c)(5) and 43 CFR 10.10(g)(2)(ii) and 10.16, the Native American Graves Protection and Repatriation Review Committee (Review Committee) may make a recommendation to the Secretary of the Interior (Secretary) for specific actions for disposition of any human remains and associated funerary objects not already addressed in 43 CFR 10.11. In April 2021, the Tennessee Valley Authority requested that the Review Committee consider a proposal to transfer control of the human remains and associated funerary objects in this notice jointly to the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation. The Review Committee carefully considered the request at its July 7, 2021 meeting and recommended to the Secretary that the proposed transfer of control proceed. An October 19, 2021 letter transmitted the Secretary's independent review and concurrence with the Review Committee that:

- Tennessee Valley Authority consulted with every appropriate Indian Tribe,
- None of The Consulted and Notified Tribes objected to the proposed transfer of control to the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation, and
- Tennessee Valley Authority may proceed with the agreed upon transfer of control of the human remains and associated funerary objects jointly to the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation.

Transfer of control is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by the Tennessee Valley Authority

Officials of the Tennessee Valley Authority have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on their presence in prehistoric archeological contexts and an osteological analysis.
- Pursuant to 25 U.S.C. 3003(e), the human remains described in this notice represent the physical remains of 74 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 4,689 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of any Indian Tribe or Native Hawaiian organization, or the ''aboriginal land of any Indian Tribe.
- Pursuant to 43 CFR 10.10(g)(2)(ii) and 10.16, the disposition of the human remains will be to the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation.
- The Tennessee Valley Authority has agreed to transfer control of the associated funerary objects to the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation.

Additional Requestors and Disposition

Representatives of any Indian Tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Thomas O. Maher, Tennessee Valley Authority, 400 West Summit Hill Drive, WT11C, Knoxville, TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov,* by December 8, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Eastern Band of Cherokee Indians and The Muscogee (Creek) Nation may proceed.

The Tennessee Valley Authority is responsible for notifying The Consulted and Notified Tribes that this notice has been published.

Dated: October 29, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24312 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032979; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Land Management, Portland, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, Bureau of Land Management (BLM) has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the BLM. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the BLM at the address in this notice by December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Dave Johnson, Bureau of Land Management, 1220 SW 3rd Avenue, Portland, OR 97204, telephone (503) 808–6596, email *cdj@blm.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the U.S. Department of the Interior, Bureau of Land Management, Portland, OR. The human remains were removed from an undisclosed location in Deschutes County, OR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by BLM professional staff in consultation with representatives of the Confederated Tribes of the Warm Springs Reservation of Oregon.

History and Description of the Remains

In 1988, human remains representing, at minimum, one individual were removed from an undisclosed location overlooking the Deschutes River in Deschutes County, OR. An unnamed family discovered the human remains and turned them over to the BLM without disclosing the exact location of the site from which the human remains were removed. No known individual was identified. No associated funerary objects are present.

According to the account of recovery of these human remains, the skeletal elements were discovered in a rockshelter along the bank of the Deschutes River. Rocks had fallen from the ceiling of the shelter and covered most of the human remains. Analyses by the Bureau of Land Management archeologist and authorities with the Deschutes County Sheriff Office determined that the skeletal remains were Native American and pre-European contact in date. The general location of the discovery is well within the ceded ancestral lands of the Confederated Tribes of the Warm Springs Reservation of Oregon.

Determinations Made by the U.S. Department of the Interior, Bureau of Land Management

Officials of the U.S. Department of the Interior, Bureau of Land Management have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Confederated Tribes of the Warm Springs Reservation of Oregon.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dave Johnson, Bureau of Land Management, 1220 SW 3rd Avenue, Portland, OR 97204, telephone (503) 808–6596, email *cdj@blm.gov,* by December 8, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Confederated Tribes of the Warm Springs Reservation of Oregon may proceed.

The U.S. Department of the Interior, Bureau of Land Management is responsible for notifying the Confederated Tribes of the Warm Springs Reservation of Oregon that this notice has been published.

Dated: October 29, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24311 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032978; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Baylor University's Mayborn Museum Complex (Formerly Baylor Museum's Strecker Museum Complex; Formerly Baylor University Museum)

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Baylor University's Mayborn Museum Complex has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Baylor University's Mayborn Museum Complex. If no additional requestors come forward, the human remains and associated funerary objects may be reinterred.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Baylor University's Mayborn Museum Complex at the address in this notice by December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Anita L. Benedict, Baylor University's Mayborn Museum Complex, One Bear Place #97154, Waco, TX 76798–7154, telephone (254) 710–4835, email *anita_benedict@baylor.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Baylor University's Mayborn Museum Complex, Waco, TX. The human remains and associated funerary objects were removed from unknown locations in Texas, and an unknown geographic location.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.9(e). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Baylor University's Mayborn Museum Complex professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Caddo Nation of Oklahoma; Comanche Nation, Oklahoma; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Jicarilla Apache Nation, New Mexico; Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; The Osage Nation [previously listed as Osage Tribe]; Tonkawa Tribe of Indians of Oklahoma; Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma; and the Ysleta del Sur Pueblo [previously listed as Ysleta del Sur Pueblo of Texas].

An invitation to consult was extended to the Alabama-Coushatta Tribe of Texas [previously listed as Alabama-Coushatta Tribes of Texas]; Alabama-Quassarte Tribal Town; Apache Tribe of Oklahoma; Cherokee Nation; Cheyenne and Arapaho Tribes, Oklahoma [previously listed as Cheyenne-Arapaho Tribes of Oklahoma]; Comanche Nation, Oklahoma; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Fort McDowell Yavapai Nation, Arizona; Fort Sill Apache Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Miccosukee Tribe of Indians; Mississippi Band of Choctaw Indians; Northern Arapaho Tribe of the Wind River Reservation, Wyoming [previously listed as Arapaho Tribe of the Wind River Reservation, Wyoming]; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Poarch Band of Creek Indians [previously known as the Poarch Band of Creeks, and as the Poarch Band of Creek Indians of Alabama]; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Seminole Tribe of Florida [previously listed as Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood, & Tampa Reservations)]; Shawnee Tribe; The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tonto Apache Tribe of Arizona; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and the Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona.

The Tribes identified above are hereafter referred to as ''The Consulted and Notified Indian Tribes.''

History and Description of the Remains

Prior to 1974, human remains representing, at minimum, five individuals were removed from an unknown location in Central or North Central Texas. The human remains and an associated funerary object were collected by an amateur archeologist. On August 5, 1974, the human remains and funerary object were donated to the Star of the Republic Museum. On October 25, 1993, the Star of the Republic Museum transferred them to the Strecker Museum. The individuals (AR 20807; AR 20917; AR 20918; AR 20919; AR 20920) are of indeterminate age and sex. No known individuals were identified. The one associated funerary object is a lot of shells, rocks, and pieces of chert (AR 20921).

Prior to 1940, human remains representing, at minimum, one individual was removed from an unknown location in Texas. The human remains and associated funerary object were collected by H. Grady Moore. The individual (AR 16526) is a child of indeterminate sex. No known individual was identified. The one associated funerary object is one animal bone fragment (AR 16532).

Prior to 1940, human remains representing, at minimum, five individuals were removed from an unknown location in Texas. The human remains were collected by H. Grady Moore. The individuals (AR 20845; AR 20925; AR 20846; AR 20923; AR 20924) are of indeterminate age and sex. No known individuals were identified. No associated funerary objects are present.

On unknown dates, human remains representing, at minimum, two individuals were removed from an unknown location in Central Texas. The human remains were likely excavated by Frank H. Watt. In 1981, Frank Watt gave permission for the portion of his collection located at the Texas Archaeological Research Laboratory (TARL) to be transferred to Baylor University (under the care of Dr. John Fox), or Dr. Fox may have acquired them from the Watt's estate after Watt's passing in 1981. Dr. John Fox was a member of Baylor University's Anthropology Department faculty. In 1985, Dr. John Fox transferred the human remains to the Strecker Museum. The individuals (AR 20836; AR 20841) are of indeterminate age and sex. No known individuals were identified. No associated funerary objects are present.

On unknown dates, human remains representing, at minimum, two individuals were removed from an unknown location in Central Texas. The human remains were likely excavated by Frank H. Watt. In 1981, Frank Watt gave permission for the portion of his collection located at the Texas Archaeological Research Laboratory (TARL) to be transferred to Baylor University where it would become part of Dr. John Fox's teaching collection. Dr. Fox was a member of Baylor University's Anthropology Department faculty. In 1991, Dr. Fox transferred the human remains to the Strecker Museum. The human remains were part of the Frank H. Watt collection, acquired from his estate or the TARL. The human remains are those of one male aged five to 13 years (AR 20837) and one female aged 10 to 11 years (AR 20838). No known individuals were identified. No associated funerary objects are present.

On unknown dates, human remains representing, at minimum, one individual, were removed from an unknown location in Central Texas. The human remains were likely excavated by Frank H. Watt. In 1995, they were transferred from the Texas Archaeological Research Laboratory (TARL) to the Strecker Museum. The human remains (AR 20840) are of indeterminate age and sex. No known individual was identified. No associated funerary objects are present.

On unknown dates, human remains representing, at minimum, three individuals, were removed from an unknown location in Central Texas. The human remains were likely excavated by Frank H. Watt. In 1981, Frank Watt gave permission for the portion of his collection located at the Texas Archaeological Research Laboratory (TARL) to be transferred to Baylor University (under the care of Dr. John Fox), or Dr. Fox may have acquired them from the Watt's estate after Watt's passing in 1981. Dr. Fox was a member of Baylor University's Anthropology Department faculty. On an unknown date, Dr. John Fox transferred the human remains to the Strecker Museum. The human remains are those of one sub-adult of indeterminate sex (AR 20827) and two individuals of indeterminate age and sex (AR 20831; AR 20842). No known individuals were identified. The two associated funerary objects are one lot of animal bone fragments (AR 20929) and one lot of shells (AR 20929).

Prior to 1961, human remains representing, at minimum, one individual were removed from an unknown geographic location. According to accession paperwork, in 1983 children found a coffin, containing a partial skeleton, in the backyard of Mrs. Mary O'Neal, in Waco, Texas. Mrs. O'Neal said her deceased husband purchased the ''Indian'' bones and the old casket about 10–15 years prior to 1961. She put them in the backyard in 1961. She told the police she did not want them, so the police took them. The police called the Museum and asked if the Strecker Museum wanted them. Calvin Smith, then Associate Director, went to the police station to accept them and the coffin. The current location of the coffin is unknown. The individual (AR 12779–A–UU) is of indeterminate age and sex. No known individual was identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, 20 individuals were removed from an unknown geographic location by an unknown individual. The individuals (AR 20814; AR 20815; AR 20816; AR 20817; AR 20818; AR 20819; AR 20820; AR 20822; AR 20824; AR 20826; AR 20828; AR 20829; AR 20832; AR 20833; AR 20834; AR 20835; AR 20839; AR 20848) are of indeterminate age and sex. Two of the individuals (AR 20926; AR 20821) are sub-adults of indeterminate sex. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown geographic location by an unknown individual. The individual (AR 20823) is of indeterminate age and sex. No known individual was identified. The one associated funerary object is a lot of mixed materials including snail shells, freshwater mollusks, glass fragment, small limestone rock, fragments non-human bone, and 4 unidentified bones fragments (AR 20927).

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown geographic location by an unknown individual. The individual (AR 20825) is of indeterminate age and sex. No known individual was identified. The one associated funerary object is an animal bone (AR 20928).

Based on the available information, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of an Indian Tribe or a Native Hawaiian organization, or the ''aboriginal land'' of an Indian Tribe pursuant to 43 CFR 10.11.

Pursuant to 25 U.S.C. 3006(c)(5) and 43 CFR 10.10(g)(2)(ii) and 10.16(a), the Native American Graves Protection and Repatriation Review Committee (Review Committee) may make a recommendation to the Secretary of the Interior (Secretary) for specific actions for disposition of any human remains and associated funerary objects not already addressed in 43 CFR 10.11. In June 2021, Baylor University's Mayborn Museum Complex requested that the Review Committee consider a proposal for the reinterment according to State or other law of the human remains and associated funerary objects described in this notice. The Review Committee carefully considered this request at its July 13, 2021 meeting and recommended to the Secretary that the proposed reinterment proceed. An October 19, 2021 letter transmitted the Secretary's independent review and concurrence with the Review Committee that:

- Baylor University's Mayborn Museum Complex consulted with every appropriate Indian Tribe,

• none of The Consulted and Notified Indian Tribes objected to the proposed re-interment, and

• Baylor University's Mayborn Museum Complex may proceed with the proposed re-interment of the human remains and associated funerary objects.

Reinterment is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by Baylor University's Mayborn Museum Complex

Officials of Baylor University's Mayborn Museum Complex have determined that:

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on museum records, the collecting history of the Museum, and the scope of the collection.

• Pursuant to 25 U.S.C. 3003(e), the human remains described in this notice represent the physical remains of 42 individuals of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(3)(A), the six objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the human remains and associated funerary objects and any present-day Indian Tribe.

• Pursuant to 43 CFR 10.11, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of any Indian Tribe or a Native Hawaiian organization, or the ''aboriginal land'' of any Indian Tribe.

• Pursuant to 43 CFR 10.10(g)(2)(ii) and 10.16, the human remains and associated funerary objects will be reinterred according to State or other law.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Anita L. Benedict, Baylor University's Mayborn Museum Complex, One Bear Place #97154, Waco, TX 76798–7154, telephone (254) 710–4835, email *anita_benedict@baylor.edu,* by December 8, 2021. After that date, if no additional requestors have come forward, the human remains and associated funerary objects may be reinterred.

Baylor University's Mayborn Museum Complex is responsible for notifying The Consulted and Notified Indian Tribes that this notice has been published.

Dated: October 29, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24314 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032968; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Boston University, Boston, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Boston University has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Boston University. If no additional requestors come forward, transfer of control of the human remains to the non-Federally recognized Indian group stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Boston University at the address in this notice by December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Kathryn M. Mellouk, Associate Vice President for Research Compliance, Boston University, One Silber Way, 9th floor, Boston, MA 02215, telephone (617) 358–4730, email *kateski@bu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of Boston University, Boston, MA. The human remains were removed from Grafton, Worcester County, MA, and from an unknown geographic location.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.9(e). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Boston University professional staff in consultation with representatives of the Mashantucket Pequot Indian Tribe [previously listed as Mashantucket Pequot Tribe of Connecticut]; Mashpee Wampanoag Tribe [previously listed as Mashpee Wampanoag Indian Tribal Council, Inc.]; Mohegan Tribe of Indians of Connecticut [previously listed as Mohegan Indian Tribe of Connecticut]; Narragansett Indian Tribe; Seminole Tribe of Florida [previously listed as Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood, & Tampa Reservations)]; Stockbridge Munsee Community, Wisconsin; Wampanoag Tribe of Gay Head (Aquinnah); and the Nipmuc Nation, Hassanamisco Band, a non-federally recognized Indian group recognized by the Commonwealth of Massachusetts. An invitation to consult was extended to the Miccosukee Tribe of Indians and The Seminole Nation of Oklahoma but they did not participate. Hereafter, all the Indian Tribes and the non-federally recognized Indian group listed in this section are referred to as ''The Consulted and Notified Tribes and Group.''

History and Description of the Remains

On an unknown date, human remains representing, at minimum, one individual were removed from Grafton, Worcester County, MA. In the spring of 2019, the human remains were found in a Boston University Archaeology Program collections storage area. No known individual was identified. No associated funerary objects are present. At the time of the excavation and removal of these human remains, the land from which the human remains were removed was not the tribal land of any Indian Tribe or Native Hawaiian organization. Boston University consulted with all Indian Tribes who are recognized as aboriginal to the area from which these Native American human remains were removed. These Tribes are the Mashantucket Pequot

Indian Tribe [previously listed as Mashantucket Pequot Tribe of Connecticut]; Mashpee Wampanoag Tribe [previously listed as Mashpee Wampanoag Indian Tribal Council, Inc.]; Mohegan Tribe of Indians of Connecticut [previously listed as Mohegan Indian Tribe of Connecticut]; Narragansett Indian Tribe; Stockbridge Munsee Community, Wisconsin; and Wampanoag Tribe of Gay Head (Aquinnah) (hereafter listed as ''The Aboriginal Land Tribes''). None of The Aboriginal Land Tribes agreed to accept control of the human remains.

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown geographic location by an unknown individual. In January of 2020, the human remains, which had been housed in the University's Archaeology Program teaching facility lab, were identified as Native American. No known individual was identified. No associated funerary objects are present. Based on the available information, the land from which these human remains were removed is not the ''tribal land'' of an Indian Tribe or a Native Hawaiian organization, or the ''aboriginal land'' of an Indian Tribe pursuant to 43 CFR 10.11.

Pursuant to 25 U.S.C. 3006(c)(5) and 43 CFR 10.10(g)(2)(ii), 10.11(c)(2)(ii)(A), and 10.16(a), the Native American Graves Protection and Repatriation Review Committee (Review Committee) may make a recommendation to the Secretary of the Interior (Secretary) for specific actions for disposition of these human remains and associated funerary objects, including transfer of control to a non-federally recognized Indian group. In June 2021, Boston University requested that the Review Committee consider a proposal to transfer control of the human remains described in this notice to the Nipmuc Nation, Hassanamisco Band, a non-federally recognized Indian group recognized by the Commonwealth of Massachusetts. The Review Committee carefully considered this request at its July 13, 2021 meeting and recommended to the Secretary that the proposed transfer of control proceed. An October 19, 2021 letter transmitted the Secretary's independent review and concurrence with the Review Committee that:

- Boston University consulted with every appropriate Indian Tribe,
- none of The Aboriginal Land Tribes agreed to accept control of the human remains from Grafton, Worcester County, MA,
- none of The Aboriginal Land Tribes objected to the proposed transfer of control to the Nipmuc Nation, Hassanamisco Band, and
- Boston University may proceed with the agreed-upon transfer of control of the human remains to the Nipmuc Nation, Hassanamisco Band, a non-federally recognized Indian group recognized by the Commonwealth of Massachusetts.

Transfer of control is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by Boston University

Officials of Boston University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on biological evidence.
- Pursuant to 25 U.S.C. 3003(e), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11, the one individual removed from Grafton, Worcester County, MA, was removed from the ''aboriginal land'' of Indian Tribes, but none of those Indian Tribes agreed to accept control of the human remains, and none of those Indian Tribes objected to the proposed transfer of control of the human remains to the Nipmuc Nation, Hassanamisco Band, a non-federally recognized Indian group.
- Pursuant to 43 CFR 10.11, the one individual removed from an unknown location was not removed from the ''tribal land'' of any Indian Tribe or Native Hawaiian organization, or the ''aboriginal land of any Indian Tribe.
- Pursuant to 43 CFR 10.10(g)(2)(ii), 10.11(c)(2)(ii), and 10.16, the disposition of the human remains will be to the Nipmuc Nation, Hassanamisco Band, a non-federally recognized Indian group recognized by the Commonwealth of Massachusetts.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Kathryn M. Mellouk, Associate Vice President for Research Compliance, Boston University, One Silber Way, 9th floor, Boston, MA 02215, telephone (617) 358–4730, email *kateski@bu.edu,* by December 8, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Nipmuc Nation, Hassanamisco Band, a non-federally recognized Indian group recognized by the Commonwealth of Massachusetts, may proceed.

Boston University is responsible for notifying The Consulted and Notified Tribes and Group, that this notice has been published.

Dated: October 29, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24313 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032962; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Fort Lewis College, Durango, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Fort Lewis College has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Office of the President, Fort Lewis College. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Office of the President, Fort Lewis College at the address in this notice by December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Kathleen Fine-Dare, NAGPRA Liaison, Office of the President, Fort Lewis

College, 1000 Rim Drive, Durango, CO 81301, telephone (970) 247–7438, email *fine_k@fortlewis.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of Fort Lewis College, Durango, CO. The human remains and associated funerary objects were removed from unknown locations, most likely in the American Southwest.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.9(e). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary objects was made by Fort Lewis professional staff in consultation with representatives of the Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Navajo Nation, Arizona, New Mexico, & Utah; Ohkay Owingeh, New Mexico [previously listed as Pueblo of San Juan]; Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Santo Domingo Pueblo [previously listed as Kewa Pueblo, New Mexico and as Pueblo of Santo Domingo]; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Ute Tribe [previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah]; Ysleta del Sur Pueblo [previously listed as Ysleta Del Sur Pueblo of Texas]; and the Zuni Tribe of the Zuni Reservation, New Mexico.

The Apache Tribe of Oklahoma; Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana; Cheyenne and Arapaho Tribes, Oklahoma [previously listed as Cheyenne-Arapaho Tribes of Oklahoma]; Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Comanche Nation, Oklahoma; Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Crow Tribe of Montana; Eastern Shoshone Tribe of the Wind River Reservation, Wyoming [previously listed as Shoshone Tribe of the Wind River Reservation, Wyoming]; Fort Sill Apache Tribe of Oklahoma; Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Northern Arapaho Tribe of the Wind River Reservation, Wyoming [previously listed as Arapaho Tribe of the Wind River Reservation, Wyoming]; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Oglala Sioux Tribe [previously listed as Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota]; Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Indian Tribe of Utah [previously listed as Paiute Indian Tribe of Utah (Cedar City Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes)]; Pawnee Nation of Oklahoma; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; San Juan Southern Paiute Tribe of Arizona; Shoshone-Bannock Tribes of the Fort Hall Reservation; Standing Rock Sioux Tribe of North & South Dakota; The Osage Nation [previously listed as Osage Tribe]; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma were invited to consult but did not participate.

Hereafter, all Indian Tribes listed in this section are referred to as ''The Consulted and Notified Tribes.''

History and Description of the Remains

Fort Lewis College is a four-year public liberal arts college located in Durango, CO. Since the 1970s, the Department of Anthropology's archeological field school has focused on sites in the southwestern United States. At times, it has also come into possession of Native American human remains and objects through undocumented donations. While the human remains of the 40 individuals described below have no documented provenience, they have been housed in Colorado for the last 30 to 89 years.

At an unknown date, human remains representing, at minimum, 26 individuals (FLC #s 501/621, 600A–B, 601–602, 606, 608, 612, 614A–B, 615, 617A–B, 619–620, 624–625, 628–633, 1000A–B, and 1006) were removed from unknown locations. On FLC #600B was written in black ink: ''UNK W45 S25.'' Exhaustive searches through college records have revealed no clues regarding the meaning of W45 S25. When the human remains came into the possession of Fort Lewis College is unknown. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual (FLC #604) were removed from an unknown location. These human remains were in a collection belonging to amateur archeologist Zeke Flora. The human remains came into the possession of Fort Lewis College in 1989. No known individuals were identified. No funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual (FLC #626) were removed from an unknown location. Unknown persons left these human remains at the Fort Lewis College Biology Department in September 1989. No known individuals were identified. No funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual (FLC #1004) were removed from an unknown location. A note associated with these human remains (two mandibular molars) indicates that they are from the ''Kroger Collection.'' When the human remains came into the possession of Fort Lewis College is unknown. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals (FLC #605A, #605B) were removed from an unknown location. The human remains came into the possession of Fort Lewis College in 1987. No known individuals were identified. The 22 associated funerary objects are 21 sherds of greyware pottery and one piece of charcoal.

At an unknown date, human remains representing, at minimum, one individual (FLC #613) were removed from an unknown location. When the human remains came into the possession of Fort Lewis College is unknown. No known individuals were identified. The 17 associated funerary objects are greyware pottery sherds.

At an unknown date, human remains representing, at minimum, seven

individuals (FLC #623A, #623B, #623C, #623D, #623D, #623E, #623F, and #623G) were removed from an unknown location. When the human remains came into the possession of Fort Lewis College is unknown. No known individuals were identified. The two associated funerary objects are one greyware pottery sherd and one lithic flake.

At an unknown date, human remains representing, at minimum, one individual (FLC #910) were removed from an unknown location. When the human remains came into the possession of Fort Lewis College is unknown. No known individuals were identified. The 10 associated funerary objects are three ladle handle fragments, one white painted sherd, one red painted sherd, four lithic flakes, and one fragment of petrified wood or stone.

Based on the available information, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of an Indian Tribe or a Native Hawaiian organization, or the ''aboriginal land'' of an Indian Tribe pursuant to 43 CFR 10.11.

Pursuant to 25 U.S.C. 3006(c)(5) and 43 CFR 10.10(g)(2)(ii) and 10.16, the Native American Graves Protection and Repatriation Review Committee (Review Committee) may make a recommendation to the Secretary of the Interior (Secretary) for specific actions for disposition of any human remains and associated funerary objects not already addressed in 43 CFR 10.11. In April 2021, Fort Lewis College requested that the Review Committee consider a proposal to transfer control of the human remains and associated funerary objects described in this notice jointly to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado and the Ute Mountain Ute Tribe [previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico, & Utah]. The Review Committee carefully considered this request at its July 7, 2021 meeting and recommended to the Secretary that the proposed transfer of control proceed. An October 19, 2021 letter transmitted the Secretary's independent review and concurrence with the Review Committee that:

- Fort Lewis College consulted with every appropriate Indian Tribe,
- None of the The Consulted and Notified Tribes objected to the proposed transfer of control to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado and the Ute Mountain Ute Tribe [previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico, & Utah], and
- Fort Lewis College may proceed with the agreed-upon transfer of control of the human remains and associated funerary objects to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado and the Ute Mountain Ute Tribe [previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico, & Utah].

Transfer of control is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by Fort Lewis College

Officials of Fort Lewis College have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on the broader collecting practices of Fort Lewis College and the findings of physical anthropologists employed by Fort Lewis College.
- Pursuant to 25 U.S.C. 3003(e), the human remains described in this notice represent the physical remains of 40 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 51 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of any Indian Tribe or Native Hawaiian organization, or the ''aboriginal land of any Indian Tribe.
- Pursuant to 43 CFR 10.10(g)(2)(ii) and 10.16, the disposition of the human remains and associated funerary objects will be to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado and the Ute Mountain Ute Tribe [previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico, & Utah].

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Kathleen Fine-Dare, NAGPRA Liaison, Office of the President, Fort Lewis College, 1000 Rim Drive, Durango, CO 81301, telephone (970) 247–7438, email *fine_k@fortlewis.edu,* by December 8, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and the Ute Mountain Ute Tribe [previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico, & Utah] may proceed.

Fort Lewis College is responsible for notifying The Consulted and Notified Tribes that this notice has been published.

Dated: October 29, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24308 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–ACAD–32771; PPNEACADSO, PPMPSPDIZ.YM0000]

Acadia National Park Advisory Commission Notice of Public Meetings

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Acadia National Park Advisory Commission (Commission) will meet as indicated below.

DATES: The Commission will meet via teleconference on Monday, February 7, 2022; Monday, June 6, 2022; and Monday, September 12, 2022. All scheduled meetings will begin at 1:00 p.m. and will end by 4:00 p.m. (Eastern).

ADDRESSES: Information on joining the teleconference will be available on the Acadia National Park website at *https://www.nps.gov/acad/getinvolved/acadia-advisory-commission.htm.*

FOR FURTHER INFORMATION CONTACT: Kathy Flanders, Superintendent's Secretary, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8702 or *kathy_flanders@nps.gov.*

SUPPLEMENTARY INFORMATION: The Commission was established by section

103 of Public Law 99–420, as amended, (16 U.S.C. 341 note), and in accordance with the Federal Advisory Committee Act (5 U.S.C. appendix 1–16). The Commission advises the Secretary of the Interior and the NPS on matters relating to the management and development of Acadia National Park, including but not limited to, the acquisition of lands and interests in lands (including conservation easements on islands) and the termination of rights of use and occupancy.

The meetings are open to the public. Interested persons may make oral presentations to the Commission. Such requests should be made to the Superintendent at the beginning of the meeting. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Written comments can be sent to Kathy Flanders [see **FOR FURTHER INFORMATION CONTACT**]. All comments received will be provided to the Commission.

Purpose of the Meeting: The Commission meeting will consist of the following proposed agenda items:

1. Superintendent's Report
2. Committee Reports:
   - Land Conservation
   - Park Use
   - Science and Education
   - Historic
3. Old Business
4. New Business
5. Chairman's Report
6. Public Comments
7. Adjournment

Public Disclosure of Information: Before including your address, phone number, email address, or other personal identifying information in your 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.

Authority: 5 U.S.C. appendix 2

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2021–24291 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032963; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Michigan State University, East Lansing, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Michigan State University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Michigan State University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Michigan State University at the address in this notice by December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Judith Stoddart, Associate Provost for University Collections and Arts Initiatives, Michigan State University, 466 W Circle Drive, East Lansing, MI 48824–1044, telephone (517) 432–2524, email *stoddart@msu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of Michigan State University, East Lansing, MI. The human remains and associated funerary objects were removed from an unknown geographic location.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.9(e). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Michigan State University professional staff in consultation with representatives of the Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Nottawaseppi Huron Band of the Potawatomi, Michigan [previously listed as Huron Potawatomi, Inc.]; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; and two non-federally recognized Indian groups, the Burt Lake Band of Ottawa and Chippewa Indians, and the Grand River Band of Ottawa Indians.

The following Indian Tribes were also invited to consult but did not participate: The Absentee-Shawnee Tribe of Indians of Oklahoma; Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Chippewa Cree Indians of the Rocky Boy's Reservation, Montana [previously listed as Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana]; Citizen Potawatomi Nation, Oklahoma; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Eastern Shawnee Tribe of Oklahoma; Forest County Potawatomi Community, Wisconsin; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Little Shell Tribe of Chippewa Indians of Montana; Menominee Indian Tribe of Wisconsin; Miami Tribe of Oklahoma; Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band;

Mille Lacs Band; White Earth Band); Ottawa Tribe of Oklahoma; Peoria Tribe of Indians of Oklahoma; Prairie Band Potawatomi Nation [previously listed as Prairie Band of Potawatomi Nation, Kansas]; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Seneca Nation of Indians [previously listed as Seneca Nation of New York]; Seneca-Cayuga Nation [previously listed as Seneca-Cayuga Tribe of Oklahoma]; Shawnee Tribe; Sokaogon Chippewa Community, Wisconsin; St. Croix Chippewa Indians of Wisconsin; Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca [previously listed as Tonawanda Band of Seneca Indians of New York]; Turtle Mountain Band of Chippewa Indians of North Dakota; and the Wyandotte Nation.

Hereafter, all the Indian Tribes and non-federally recognized Indian groups listed in this section are referred to as ''The Consulted and Notified Tribes and Groups.''

History and Description of the Remains

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown geographic location. The human remains (2004.46.21) were acquired by Kalamazoo resident Donald Boudeman, who had collected Southwest Native American material culture during the first half of the twentieth century. In July of 1961, some years after her husband's death, Donna Boudeman donated the human remains (and parts of Mr. Boudeman's collection) to Michigan State University Museum. No known individual was identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, eight individuals were removed from an unknown geographic location. The human remains (20323; 6497 CW; 6504 CW; 6508 CW; 6509 CW; 6510 CW; 6511 CW; 6587 CW) were acquired by the Chamberlain Memorial Museum in Three Oaks, Michigan. (The Chamberlain Memorial Museum was founded in 1916 by Mr. Edward K. Warren.) In September of 1952, Michigan State College Museum (now Michigan State University Museum) acquired the contents of the Chamberlain Memorial Museum from Fred P. Warren, President of the Board of Trustees of the E. K. Warren Foundation. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown location. The human remains (2693.12) were acquired by the Chamberlain Memorial Museum. In September of 1952, Michigan State College Museum (now the Michigan State University Museum) acquired the contents of the Chamberlain Memorial Museum. No known individual was identified. The two associated funerary objects are one scraper (2693.28) and one lot of mica, biface, pendant, and adze (2693.28).

On an unknown date, human remains representing, at minimum, two individuals were removed from a mound in an unknown location. H. Bradley acquired the human remains (6499 CW) and subsequently gave them to the Chamberlain Memorial Museum. In September of 1952, Michigan State College Museum (now Michigan State University Museum) acquired the contents of the Chamberlain Memorial Museum. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown location. In July of 2019, the human remains (UP4) were discovered when cleaning out the office of former Michigan State University Anthropology Professor Dr. Norman Sauer. The box containing the remains was labeled ''red ochre bones.'' No known individual was identified. The one associated funerary object is one worked and polished slate (UP4).

On an unknown date, human remains representing, at minimum, eight individuals were removed from an unknown location. On October 4, 2017, the human remains (NA #1A; NA #1B) were found in the Michigan State University's Forensic Anthropology Laboratory. No known individuals were identified. The two associated funerary objects are one lot of grit-tempered sherds (NA #1A; NA #1B) and one lot of modified shell (NA #1A; NA #1B).

On an unknown date, human remains representing, at minimum, 15 individuals were removed from an unknown location. On October 4, 2017, the human remains (4; 6; 634M (vault absent); 634M (vault present); MC2–1; MC2–2; MC2–3; MC3–1; MC3–2; MC4; UP3) were found in the Michigan State University's Forensic Anthropology Laboratory. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown location. On October 4, 2017, the human remains (UP1) were found in the Michigan State University's Forensic Anthropology Laboratory. No known individual was identified. The two associated funerary objects are one lot of fabric (UP1) and one lot of buttons (UP1).

On an unknown date, human remains representing, at minimum, two individuals were removed from an unknown location. On October 4, 2017, the human remains (UP2) were found in the Michigan State University's Forensic Anthropology Laboratory. No known individuals were identified. The four associated funerary objects are two lithics (UP2), one gorget (UP2), and one unidentified animal bone (UP2).

On an unknown date, human remains representing, at minimum, three individuals were removed from an unknown location. On October 4, 2017, the human remains (31.2576; 31.2576–96) were found in the Michigan State University's Forensic Anthropology Laboratory. A number associated with these remains resembles a police case number, but no such case could be located. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, one individual were removed from an unknown location. On September 20, 2018, the MSU Forensic Anthropology Laboratory received the human remains (FA 005–19) from the Department of Human Anatomy at Michigan State University. No known individual was identified. No associated funerary objects are present.

Based on the available information, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of an Indian Tribe or a Native Hawaiian organization, or the ''aboriginal land'' of an Indian Tribe pursuant to 43 CFR 10.11.

Pursuant to 25 U.S.C. 3006(c)(5) and 43 CFR 10.10(g)(2)(ii) and 10.16, the Native American Graves Protection and Repatriation Review Committee (Review Committee) may make a recommendation to the Secretary of the Interior (Secretary) for specific actions for disposition of any human remains and associated funerary objects not already addressed in 43 CFR 10.11. In June 2021, Michigan State University requested that the Review Committee consider a proposal to transfer control of the human remains and associated funerary objects in this notice jointly to

the Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan and the Sault Ste. Marie Tribe of Chippewa Indians, Michigan. The Review Committee carefully considered the request at its July 7, 2021 meeting and recommended to the Secretary that the proposed transfer of control proceed. An October 19, 2021 letter transmitted the Secretary's independent review and concurrence with the Review Committee that:

- Michigan State University consulted with every appropriate Indian Tribe,
- None of The Consulted and Notified Tribes and Groups objected to the proposed transfer of control to the Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan and the Sault Ste. Marie Tribe of Chippewa Indians, Michigan, and
- Michigan State University may proceed with the agreed upon transfer of control of the human remains and associated funerary objects to the Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan and the Sault Ste. Marie Tribe of Chippewa Indians, Michigan.

Transfer of control is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by Michigan State University

Officials of Michigan State University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on biological evidence and museum and lab records.
- Pursuant to 25 U.S.C. 3003(e), the human remains described in this notice represent the physical remains of 43 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 11 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11, the land from which these human remains and associated funerary objects were removed is not the ''tribal land'' of any Indian Tribe or Native Hawaiian organization, or the ''aboriginal land of any Indian Tribe.
- Pursuant to 43 CFR 10.10(g)(2)(ii) and 10.16, the disposition of the human remains and associated funerary objects will be to the Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan and the Sault Ste. Marie Tribe of Chippewa Indians, Michigan.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Judith Stoddart, Associate Provost for University Collections and Arts Initiatives, Michigan State University, 466 W Circle Drive, East Lansing, MI 48824–1044, telephone (517) 432–2524, email *stoddart@msu.edu,* by December 8, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan and the Sault Ste. Marie Tribe of Chippewa Indians, Michigan, may proceed.

Michigan State University is responsible for notifying The Consulted and Notified Tribes and Groups that this notice has been published.

Dated: October 29, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24306 Filed 11–5–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Z-Wave Alliance, Inc.

Notice is hereby given that, on October 6, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Z-Wave Alliance, Inc. (the ''Joint Venture'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Specifically, DEN Smart Home, Enchede, THE NETHERLANDS; Evalan BV, Amsterdam, THE NETHERLANDS; Guangzhou MCOHome Technology Co., LTD, Guangzhou, PEOPLE'S REPUBLIC OF CHINA; Hubbell, Shelton, CT; Shenzhen Sunricher Technology Limited, Shenzhen, PEOPLE'S REPUBLIC OF CHINA; Shenzhen ZVIDAR Technologies CO., LTD., Shenzhen City, PEOPLE'S REPUBLIC OF CHINA; Takacs Milan EV, Szigetmonostor, HUNGARY; and Worthington Distribution, Tafton, PA have joined as parties to the venture. Also, Ohlandt Consulting, Laytonsville, MD; Lynx Integrated Systems, Malaga, AUSTRALIA; Remote Technologies Inc, Shakopee, MN; Smart Dalton, Riyadh, SAUDI ARABIA; Custom Smart Automation, West Hoxton, AUSTRALIA; Nanjing IoTx Intelligent Technology Co., Ltd., Nanjing, PEOPLE'S REPUBLIC OF CHINA; Brittworks, Richmond, CA; Askey Computer Group, New Taipei City, TAIWAN; Guangzhou MCOHome Technology Co., LTD, Guangzhou, PEOPLE'S REPUBLIC OF CHINA; Spectrum Smart Solutions LLC, Ajman, UNITED ARAB EMIRATES; KJ Robotics, Hedehusene, DENMARK; Coqon GmbH, Bonn, GERMANY; Life2Better, Buenos Aires, ARGENTINA; and Smart at Home, Pullenvale, AUSTRALIA have withdrawn as parties to the venture.

In addition, Smart Home SA, Gland, SWITZERLAND was mistakenly reported on the last filing (86 FR 47150) as a withdrawn party to this venture, and remains as an existing party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and the Joint Venture intends to file additional written notifications disclosing all changes in membership.

On November 19, 2020, the Joint Venture filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 1, 2020 (85 FR 77241).

The last notification was filed with the Department on July 16, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 23, 2021 (86 FR 47150).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–24380 Filed 11–5–21; 8:45 am]

BILLING CODE 4410–11–P

LEGAL SERVICES CORPORATION

Notice of Intent To Award—Grant Awards for the Delivery of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2022

AGENCY: Legal Services Corporation.

ACTION: Announcement of the Legal Services Corporation's intent to make FY2022 Grant Awards.

SUMMARY: The Legal Services Corporation (LSC) hereby announces its intention to award grants to provide effective and efficient delivery of high-quality civil legal services to eligible low-income clients, starting January 1, 2022.

DATES: All comments and recommendations must be received on or before the close of business on December 8, 2021.

ADDRESSES: Grant Awards, Legal Services Corporation; 3333 K Street NW, Third Floor; Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Judith Lee, Grants Program Manager, Office of Program Performance, at (202) 295–1518 or *leej@lsc.gov.*

SUPPLEMENTARY INFORMATION: Under LSC's Notice of Funds Available published on March 15, 2021 (86 FR 14344) and LSC's grant application process beginning on May 3, 2021, LSC intends to award funds to organizations that provide civil legal services in the indicated service areas. Applicants for each service area are listed below. The grant award amounts below are estimates based on the FY2021 grant awards to each service area. The funding estimates may change based on the final FY2022 appropriation. In addition, Agricultural Worker service area population estimates are subject to change based on Department of Labor review and comments LSC receives during the 30-day comment period.

LSC will post all updates and changes to this notice at *https://www.lsc.gov/grants/basic-field-grant/basic-field-awards.* Interested parties are asked to visit *https://www.lsc.gov/grants/basic-field-grant* regularly for updates on the LSC grants process.

Name of applicant organization	State	Service area	Estimated annualized 2022 funding
Alaska Legal Services Corporation	AK	AK–1	$988,604
Alaska Legal Services Corporation	AK	NAK–1	672,243
Legal Services Alabama, Inc	AL	AL–4	7,043,648
Legal Aid of Arkansas, Inc	AR	AR–6	1,749,877
Center for Arkansas Legal Services	AR	AR–7	2,622,075
American Samoa Legal Aid	AS	AS–1	319,432
DNA-Peoples Legal Services, Inc	AZ	AZ–2	531,382
Community Legal Services, Inc	AZ	AZ–3	6,191,200
Southern Arizona Legal Aid, Inc	AZ	AZ–5	2,483,867
Community Legal Services, Inc	AZ	MAZ	418,446
DNA-Peoples Legal Services, Inc	AZ	NAZ–5	3,243,604
Southern Arizona Legal Aid, Inc	AZ	NAZ–6	792,319
California Indian Legal Services, Inc	CA	CA–1	35,855
Inland Counties Legal Services, Inc	CA	CA–12	5,078,679
Legal Aid Society of San Diego, Inc	CA	CA–14	3,049,856
Community Legal Aid SoCal	CA	CA–19	3,813,965
Greater Bakersfield Legal Assistance, Inc	CA	CA–2	1,329,802
Central California Legal Services	CA	CA–26	3,319,023
Legal Services of Northern California, Inc	CA	CA–27	4,294,610
Bay Area Legal Aid	CA	CA–28	4,534,544
Legal Aid Foundation of Los Angeles	CA	CA–29	6,537,332
Neighborhood Legal Services of Los Angeles County	CA	CA–30	4,426,887
California Rural Legal Assistance, Inc	CA	CA–31	5,170,213
California Rural Legal Assistance, Inc	CA	MCA	4,129,707
California Indian Legal Services, Inc	CA	NCA–1	1,098,192
Colorado Legal Services	CO	CO–6	5,009,557
Colorado Legal Services	CO	MCO	282,481
Colorado Legal Services	CO	NCO–1	119,375
Statewide Legal Services of Connecticut, Inc	CT	CT–1	3,417,826
Pine Tree Legal Assistance, Inc	CT	NCT–1	19,461
Neighborhood Legal Services Program of the District of Columbia	DC	DC–1	909,170
Legal Services Corporation of Delaware, Inc	DE	DE–1	1,038,696
Maryland Legal Aid	DE	MDE	29,643
Legal Services of North Florida, Inc	FL	FL–13	2,013,108
Three Rivers Legal Services, Inc	FL	FL–14	2,614,378
Community Legal Services of Mid-Florida, Inc	FL	FL–15	5,519,211
Bay Area Legal Services, Inc	FL	FL–16	4,284,672
Florida Rural Legal Services, Inc	FL	FL–17	4,662,878
Coast to Coast Legal Aid of South Florida, Inc	FL	FL–18	2,633,141
Legal Services of Greater Miami, Inc	FL	FL–5	4,111,204
Florida Rural Legal Services, Inc	FL	MFL	921,607
Atlanta Legal Aid Society, Inc	GA	GA–1	4,041,147
Georgia Legal Services Program	GA	GA–2	9,120,494
Georgia Legal Services Program	GA	MGA	635,435
Micronesian Legal Services Corporation	GU	GU–1	359,993
Legal Aid Society of Hawaii	HI	HI–1	1,488,123
Legal Aid Society of Hawaii	HI	NHI–1	284,737
Iowa Legal Aid	IA	IA–3	3,162,859
Iowa Legal Aid	IA	MIA	267,706
Idaho Legal Aid Services, Inc	ID	ID–1	1,579,021

Name of applicant organization	State	Service area	Estimated annualized 2022 funding
Idaho Legal Aid Services, Inc	ID	MID	389,099
Idaho Legal Aid Services, Inc	ID	NID–1	80,756
Land of Lincoln Legal Aid, Inc	IL	IL–3	3,066,885
Legal Aid Chicago	IL	IL–6	6,490,201
Prairie State Legal Services, Inc	IL	IL–7	4,458,815
Legal Aid Chicago	IL	MIL	249,444
Indiana Legal Services, Inc	IN	IN–5	7,614,406
Indiana Legal Services, Inc	IN	MIN	176,583
Kansas Legal Services, Inc	KS	KS–1	3,245,538
Legal Aid of the Bluegrass	KY	KY–10	1,775,914
Legal Aid Society	KY	KY–2	1,540,306
Appalachian Research and Defense Fund of Kentucky	KY	KY–5	1,926,311
Kentucky Legal Aid	KY	KY–9	1,547,495
Southeast Louisiana Legal Services Corporation	LA	LA–13	3,977,231
Acadiana Legal Service Corporation	LA	LA–15	4,332,826
Community Legal Aid, Inc	MA	MA–10	1,701,972
Volunteer Lawyers Project of the Boston Bar Association	MA	MA–11	2,439,092
South Coastal Counties Legal Services	MA	MA–12	1,139,906
Northeast Legal Aid, Inc	MA	MA–4	927,104
Maryland Legal Aid	MD	MD–1	5,212,623
Maryland Legal Aid	MD	MMD	132,236
Pine Tree Legal Assistance, Inc	ME	ME–1	1,328,595
Pine Tree Legal Assistance, Inc	ME	MMX–1	336,418
Pine Tree Legal Assistance, Inc	ME	NME–1	80,118
Michigan Advocacy Program	MI	MI–12	1,983,548
Lakeshore Legal Aid	MI	MI–13	4,845,857
Legal Services of Eastern Michigan	MI	MI–14	1,881,251
Legal Aid of Western Michigan	MI	MI–15	2,505,773
Legal Services of Northern Michigan, Inc	MI	MI–9	899,382
Michigan Advocacy Program	MI	MMI	628,341
Michigan Indian Legal Services, Inc	MI	NMI–1	204,622
Southern Minnesota Regional Legal Services, Inc	MN	MMN	481,867
Legal Aid Service of Northeastern Minnesota	MN	MN–1	478,750
Legal Services of Northwest Minnesota Corporation	MN	MN–4	404,936
Southern Minnesota Regional Legal Services, Inc	MN	MN–5	1,749,508
Central Minnesota Legal Services, Inc	MN	MN–6	1,852,613
Anishinabe Legal Services, Inc	MN	NMN–1	297,058
Legal Aid of Western Missouri	MO	MMO	184,272
Legal Aid of Western Missouri	MO	MO–3	2,483,427
Legal Services of Eastern Missouri, Inc	MO	MO–4	2,206,494
Mid-Missouri Legal Services Corporation	MO	MO–5	619,693
Legal Services of Southern Missouri	MO	MO–7	2,240,364
Micronesian Legal Services Corporation	MP	MP–1	1,805,376
Mississippi Center for Legal Services	MS	MS–10	3,245,910
North Mississippi Rural Legal Services, Inc	MS	MS–9	2,083,786
Mississippi Center for Legal Services	MS	NMS–1	103,326
Montana Legal Services Association	MT	MMT	158,178
Montana Legal Services Association	MT	MT–1	1,166,187
Montana Legal Services Association	MT	NMT–1	197,922
Legal Aid of North Carolina, Inc	NC	MNC	715,604
Legal Aid of North Carolina, Inc	NC	NC–5	13,204,088
Legal Aid of North Carolina, Inc	NC	NNC–1	271,283
Southern Minnesota Regional Legal Services, Inc	ND	MND	124,781
Legal Services of North Dakota	ND	ND–3	659,616
Legal Services of North Dakota	ND	NND–3	334,836
Legal Aid of Nebraska	NE	MNE	213,558
Legal Aid of Nebraska	NE	NE–4	1,651,880
Legal Aid of Nebraska	NE	NNE–1	41,088
603 Legal Aid	NH	NH–1	929,520
South Jersey Legal Services, Inc	NJ	MNJ	157,627
Legal Services of Northwest Jersey, Inc	NJ	NJ–15	623,172
Central Jersey Legal Services, Inc	NJ	NJ–17	1,623,397
Northeast New Jersey Legal Services Corporation	NJ	NJ–18	2,061,143
South Jersey Legal Services, Inc	NJ	NJ–20	2,482,498
Essex-Newark Legal Services Project, Inc	NJ	NJ–8	1,068,449
New Mexico Legal Aid	NM	MNM	185,850
DNA-Peoples Legal Services, Inc	NM	NM–1	247,673
New Mexico Legal Aid	NM	NM–5	3,314,527
DNA-Peoples Legal Services, Inc	NM	NNM–2	28,241
New Mexico Legal Aid	NM	NNM–4	577,556
Nevada Legal Services, Inc	NV	NNV–1	165,289
Nevada Legal Services, Inc	NV	NV–1	3,811,667

Name of applicant organization	State	Service area	Estimated annualized 2022 funding
Legal Aid Society of Mid-New York, Inc	NY	MNY	333,772
Legal Services of the Hudson Valley	NY	NY–20	2,217,165
Legal Aid Society of Northeastern New York, Inc	NY	NY–21	1,724,049
Legal Aid Society of Mid-New York, Inc	NY	NY–22	2,156,089
Legal Assistance of Western New York, Inc	NY	NY–23	2,133,155
Neighborhood Legal Services, Inc	NY	NY–24	1,570,542
Nassau/Suffolk Law Services Committee, Inc	NY	NY–7	1,641,227
Legal Services NYC	NY	NY–9	12,998,155
Legal Aid of Western Ohio, Inc	OH	MOH	217,268
Legal Aid Society of Greater Cincinnati	OH	OH–18	2,041,668
Community Legal Aid Services, Inc	OH	OH–20	2,434,880
The Legal Aid Society of Cleveland	OH	OH–21	2,789,400
Legal Aid of Western Ohio, Inc	OH	OH–23	3,410,218
Ohio State Legal Services	OH	OH–24	4,017,874
Legal Aid Services of Oklahoma, Inc	OK	MOK	296,145
Oklahoma Indian Legal Services, Inc	OK	NOK–1	1,017,770
Legal Aid Services of Oklahoma, Inc	OK	OK–3	5,558,758
Legal Aid Services of Oregon	OR	MOR	565,177
Legal Aid Services of Oregon	OR	NOR–1	229,462
Legal Aid Services of Oregon	OR	OR–6	4,161,133
Philadelphia Legal Assistance Center	PA	MPA	425,150
Philadelphia Legal Assistance Center	PA	PA–1	3,502,766
Southwestern Pennsylvania Legal Services, Inc	PA	PA–11	527,937
Legal Aid of Southeastern Pennsylvania	PA	PA–23	1,629,668
North Penn Legal Services, Inc	PA	PA–24	2,439,623
MidPenn Legal Services, Inc	PA	PA–25	3,058,932
Northwestern Legal Services	PA	PA–26	875,277
Laurel Legal Services, Inc	PA	PA–5	828,493
Neighborhood Legal Services Association	PA	PA–8	1,668,402
Puerto Rico Legal Services, Inc	PR	MPR	64,069
Puerto Rico Legal Services, Inc	PR	PR–1	13,447,567
Community Law Office, Inc	PR	PR–2	314,564
Rhode Island Legal Services, Inc	RI	RI–1	1,099,457
South Carolina Legal Services, Inc	SC	MSC	285,850
South Carolina Legal Services, Inc	SC	SC–8	6,670,833
Dakota Plains Legal Services, Inc	SD	NSD–1	1,160,609
East River Legal Services	SD	SD–2	482,578
Dakota Plains Legal Services, Inc	SD	SD–4	541,174
Legal Aid Society of Middle Tennessee and the Cumberlands	TN	TN–10	3,630,964
Memphis Area Legal Services, Inc	TN	TN–4	1,631,652
West Tennessee Legal Services, Inc	TN	TN–7	774,923
Legal Aid of East Tennessee	TN	TN–9	2,991,648
Texas RioGrande Legal Aid, Inc	TX	MSX–2	2,983,235
Texas RioGrande Legal Aid, Inc	TX	NTX–1	38,904
Lone Star Legal Aid	TX	TX–13	13,950,655
Legal Aid of NorthWest Texas	TX	TX–14	10,655,452
Texas RioGrande Legal Aid, Inc	TX	TX–15	13,146,377
Utah Legal Services, Inc	UT	MUT	110,742
Utah Legal Services, Inc	UT	NUT–1	102,263
Utah Legal Services, Inc	UT	UT–1	2,713,928
Central Virginia Legal Aid Society, Inc	VA	MVA	320,155
Southwest Virginia Legal Aid Society, Inc	VA	VA–15	974,623
Legal Aid Society of Eastern Virginia	VA	VA–16	1,650,677
Virginia Legal Aid Society, Inc	VA	VA–17	943,058
Central Virginia Legal Aid Society, Inc	VA	VA–18	1,437,875
Blue Ridge Legal Services, Inc	VA	VA–19	958,213
Legal Services of Northern Virginia, Inc	VA	VA–20	1,977,868
Legal Services of the Virgin Islands, Inc	VI	VI–1	237,227
Legal Services Vermont	VT	VT–1	554,061
Northwest Justice Project	WA	MWA	1,027,455
Northwest Justice Project	WA	NWA–1	354,095
Northwest Justice Project	WA	WA–1	6,305,760
Legal Action of Wisconsin, Inc	WI	MWI	484,838
Wisconsin Judicare, Inc	WI	NWI–1	192,819
Wisconsin Judicare, Inc	WI	WI–2	1,119,796
Legal Action of Wisconsin, Inc	WI	WI–5	4,335,175
Legal Aid of West Virginia, Inc	WV	WV–5	2,799,112
Legal Aid of Wyoming, Inc	WY	NWY–1	214,798
Legal Aid of Wyoming, Inc	WY	WY–4	571,853

These grants will be awarded under the authority conferred on LSC by section 1006(a)(1) of the Legal Services Corporation Act, 42 U.S.C. 2996e(a)(l). Grant awards are made to ensure civil legal services are provided in every service area, although no listed organization is guaranteed a grant award. Grants will become effective, and grant funds will be distributed, on or about January 1, 2022.

LSC issues this notice pursuant to 42 U.S.C. 2996f(f). Comments and recommendations concerning potential grantees are invited and should be delivered to LSC within 30 days from the date of publication of this notice.

Dated: November 3, 2021.

Mark Freedman,

Senior Associate General Counsel.

[FR Doc. 2021–24383 Filed 11–5–21; 8:45 am]

BILLING CODE 7050–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0170]

Acceptable Standard Format and Content for the Fundamental Nuclear Material Control Plan Required for Special Nuclear Material of Moderate Strategic Significance

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment; extension of comment period.

SUMMARY: On September 23, 2021, the U.S. Nuclear Regulatory Commission (NRC) issued for public comment draft NUREG, NUREG–2159, Revision 1, ''Acceptable Standard Format and Content for the Fundamental Nuclear Material Control Plan Required for Special Nuclear Material of Moderate Strategic Significance.'' The public comment period was originally scheduled to close on November 22, 2021. The NRC has decided to extend the public comment period to allow more time for members of the public to develop and submit their comments.

DATES: The due date of comments requested in the document published on September 23, 2021 (86 FR 52926) is extended. Comments should be filed no later than December 3, 2021. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking Website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0170. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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

FOR FURTHER INFORMATION CONTACT: Tom Pham, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7254, email: *Tom.Pham@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0170 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0170.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ''Acceptable Standard Format and Content for the Fundamental Nuclear Material Control Plan Required for Special Nuclear Material of Moderate Strategic Significance,'' draft NUREG–2159, Revision 1, is available in ADAMS under Accession No. ML21263A119.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0170 in your comment submission.

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

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

II. Discussion

Draft NUREG–2159, Revision 1, provides guidance to facilitate compliance with applicable provisions in Subpart D of Part 74 of title 10 of the *Code of Federal Regulations,* ''Material Control and Accounting of Special Nuclear Material.'' Draft NUREG–2159, Revision 1, provides guidance for fuel cycle and other licensees and applicants who may request authorization to hold SNM of moderate strategic significance. Generally, this draft guidance document discusses acceptable methods licensees and applicants may use to prepare and implement their fundamental nuclear material control plans, and how the NRC will review and inspect these plans. The public comment period was originally scheduled to close on November 22, 2021. The NRC has decided to extend the public comment period on this document until December 3, 2021, to allow more time for members of the public to submit their comments.

Dated: November 3, 2021.

For the Nuclear Regulatory Commission.

James L. Rubenstone,

Chief, Material Control and Accounting Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–24389 Filed 11–5–21; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022–17 and CP2022–18; MC2022–18 and CP2022–19]

New Postal Product

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:* November 10, 2021.

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
II. Docketed Proceeding(s)

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).:* MC2022–17 and CP2022–18; *Filing Title:* USPS Request to Add Parcel Select and Parcel Return Service Contract 14 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Katalin K. Clendenin; *Comments Due:* November 10, 2021.

2. *Docket No(s).:* MC2022–18 and CP2022–19; *Filing Title:* USPS Request to Add Priority Mail Contract 727 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 2, 2021; *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:* November 10, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–24338 Filed 11–5–21; 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).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93506; File No. SR–PEARL–2021–35]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Exchange Rule 2616, Priority of Orders

November 2, 2021.

I. Introduction

On July 20, 2021, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rule (''Rule'') 2616, Priority of Orders, to provide that an order receive a new timestamp when its position is modified via a Cancel/Replace message during a short sale period. The proposed rule change was published for comment in the **Federal Register** on August 6, 2021.[3] On September 16, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On September 28, 2021, the Exchange filed Amendment No. 1 to the proposed rule change.[6] The Commission has received no comments on the proposed rule change. This order provides notice of the filing of Amendment No. 1 to the proposed rule change, and grants approval to the proposed rule change, as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92545 (August 2, 2021), 86 FR 43279 (August 6, 2021) (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 93024 (September 16, 2021), 86 FR 52704 (September 22, 2021). The Commission designated November 4, 2021, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] In Amendment No. 1, the Exchange amended the proposal to: (1) Provide additional explanation and rationale for the proposed rule change; (2) describe how the proposed rule change should have minimal impact based on past trading activity on the Exchange; (3) enhance statements concerning each equity member's obligations to comply with Regulation SHO (17 CFR 242.200 *et seq.*); and (4) correct minor typographical errors. Amendment No. 1 is available on the Commission's website at *https://www.sec.gov/comments/sr-pearl-2021-35/srpearl202135-9304453-259866.pdf.*

modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

Rule 2616(a)(5) currently provides that, in the event an order has been cancelled or replaced in accordance with Rule 2614(e), such order only retains its timestamp if such modification involves a decrease in the size of the order, a change to the Max Floor of an order with a Reserve Quantity, or a change in position from (A) sell to sell short; (B) sell to sell short exempt; (C) sell short to sell; (D) sell short to sell short exempt; (E) sell short exempt to sell; and (F) sell short exempt to sell short.[7] Under the current rule, any other modification to an order, including an increase in the size of the order and/or price change, results in such order losing time priority as compared to other orders in the MIAX Pearl Equities Book and the timestamp for such order being revised to reflect the time of the modification.[8]

The Exchange has proposed to amend Rule 2616(a)(5) such that an order resting on the MIAX Pearl Equities trading platform that is modified via a Cancel/Replace message,[9] in accordance with Rule 2614(e), to change its position in one of the ways enumerated in Rule 2616(a)(5) would retain its timestamp only if the position change occurs when a short sale period is not in effect (and there is no additional modification to the order that would trigger a new timestamp, such as an increase in size or price change).[10] As a result, unlike under the current rule, under proposed Rule 2616(a)(5) an order that is modified via a Cancel/Replace message, in accordance with Rule 2614(e), to change its position as enumerated in Rule 2616(a)(5) would receive a new timestamp when the position change occurs during a short sale period, even if, for example, the order's price remains unchanged.[11] Such modification to an order during a short sale period would result in the order losing time priority compared to other orders in the MIAX Pearl Equities Book and the timestamp for such order being revised to reflect the time of the modification.[12]

The Exchange states that this proposed rule change stems from changes to the underlying technology for its re-pricing processes for the displayed and non-displayed portions of an order with a Reserve Quantity,[13] which, in turn, impacted how its system determines whether a short sale order must be re-priced to comply with Regulation SHO.[14] The Exchange further states that, due to these technology changes and the interaction and technological complexity of its system's order re-pricing processes, this proposal would entail adjusting the Exchange's re-pricing process to re-evaluate an order for execution when the order's position is modified, via a Cancel/Replace message, during a short sale period and there is no corresponding change to the order's price.[15] This, according to the Exchange, would result in the order receiving a new timestamp, including where the order's price remains unchanged.[16] According to the Exchange, it has proposed this rule change in an abundance of caution to reinforce the reliability, resiliency, and continued operation of its system and underlying technology.[17]

In addition, the Exchange states that the proposed rule change is designed to address a discrete and potentially limited scenario, and states, by way of example, that between July 1, 2021 and September 7, 2021, there were no position modifications via a Cancel/Replace message that would have resulted in a new timestamp and loss in priority based on the proposed functionality, had it been in effect.[18] Further, the Exchange states that a change in an order's price or position as well as an increase in an order's size via a Cancel/Replace message implicitly result in a new order, and all Exchange equity members therefore must ensure continued compliance with the order marking and locate requirements of Regulation SHO, including compliance with Question 2.6 of the Commission's ''Responses to Frequently Asked Questions Concerning Regulation SHO.''[19]

The Exchange also has proposed to replace the phrase ''cancelled or replaced'' in Rule 2616(a)(5) with the phrase ''modified via a Cancel/Replace message,'' so as to clarify within Rule 2616(a)(5) that the order is being modified, rather than cancelled and replaced with a new order.[20] Relatedly, the Exchange has proposed a conforming change to Rule 2614(e)(3) to add the word ''Cancel'' before the word ''Replace'' to make its rulebook terminology consistent in referring to a ''Cancel/Replace message.''[21] The Exchange states that these proposed changes do not amend the meaning or operation of either rule.[22]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[23] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[24] 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 that those rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange has proposed to amend Rule 2616(a)(5) such that an order resting on the MIAX Pearl Equities trading platform would receive a new timestamp when the order's position is modified via a Cancel/Replace message during a short sale period regardless of whether there is a corresponding change to the order's price. The Commission believes that this proposal should facilitate the

[7] *See* Rule 2616(a)(5); Notice at 43280.

[8] *See* Rule 2616(a)(5); Notice at 43280.

[9] As discussed below, the Exchange proposes to replace the phrase ''cancelled or replaced'' in Rule 2616(a)(5) with the phrase ''modified via a Cancel/Replace message.''

[10] *See* proposed Rule 2616(a)(5); Notice at 43280. *See also* Rule 2614(g)(3)(A) (stating that a short sale period is the time when ''a short sale price test restriction under Rule 201 of Regulation SHO'' is in effect); 17 CFR 242.201.

[11] *See* proposed Rule 2616(a)(5); Notice at 43280.

[12] *See* proposed Rule 2616(a)(5); Notice at 43280.

[13] *See* Amendment No. 1, at 3.

[14] *See id.* at 3–4. *See also* 17 CFR 242.201; Rule 2614(g)(3)(C) (setting forth the Exchange's short sale price sliding process).

[15] *See* Amendment No. 1, at 4–5. The Exchange states that, currently, an order is not re-evaluated for execution when its position is modified unless the order receives a new price. *See id.* at 5 n.7.

[16] *Id.* at 4–5.

[17] *Id.*

[18] *Id.* at 5–6.

[19] *Id.* at 7. *See also* 17 CFR 242.201; Responses to Frequently Asked Questions Concerning Regulation SHO, *available at: https://www.sec.gov/divisions/marketreg/mrfaqregsho1204.htm.*

[20] *See* proposed Rule 2616(a)(5); *see also* Notice at 43280.

[21] *See* proposed Rule 2614(e)(3); *see also* Notice at 43280.

[22] *See* Notice at 43280.

[23] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[24] 15 U.S.C. 78f(b)(5).

Exchange's ability to fulfill its regulatory obligations, particularly with regard to the operation and resilience of its system and compliance with Regulation SHO. Moreover, the Exchange has represented, and assessed historical practices on the Exchange to verify, that it likely would be an uncommon occurrence for an order to lose time priority as a result of the change in functionality proposed herein. Thus, the proposed rule change appears to be designed to implicate a discrete and limited order book scenario. Further, the Commission believes that the proposed functionality, in addition to likely being implicated infrequently, will be fully transparent to market participants. Lastly, the Commission believes that the proposed change to Rule 2616(a)(5) to replace the phrase ''cancelled or replaced'' with the phrase ''modified via a Cancel/Replace message'' and the proposed conforming change to Rule 2614(e)(3) should enhance the clarity and consistency of the terminology used in the Exchange's rules, which should help mitigate the potential for market participant confusion.

For the reasons discussed above, the Commission finds that this proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, and is not designed to permit unfair discrimination.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–PEARL–2021–35 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 No. SR–PEARL–2021–35. The file numbers should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File No. SR–PEARL–2021–35 and should be submitted on or before November 29, 2021.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the amended proposal in the **Federal Register**. In Amendment No. 1, the Exchange amended the proposal to: (1) Provide additional explanation and rationale for the proposed rule change; (2) describe how the proposed rule change should have minimal impact based on past trading activity on the Exchange; (3) enhance statements concerning each equity member's obligations to comply with Regulation SHO; and (4) correct minor typographical errors. Amendment No. 1 adds clarity and justification to the proposal, and does not alter the proposed change in system functionality from what is set forth in the Notice, which was subject to a full comment period. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[25] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[26] that the proposed rule change (SR–PEARL–2021–35), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24325 Filed 11–5–21; 8:45 am]

BILLING CODE 8011–01–P

[25] 15 U.S.C. 78s(b)(2).

[26] *Id.*

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93505; File No. SR–IEX–2021–13]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend IEX Rule 11.330 To Retire the IEX Data Platform Data Product

November 2, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 25, 2021, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[4] and Rule 19b–4 thereunder,[5] IEX is filing with the Commission proposed changes to IEX Rule 11.330 to retire the IEX Data Platform data product. The Exchange has designated this rule change as ''non-controversial'' under Section 19(b)(3)(A)

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

of the Act[6] and provided the Commission with the notice required by Rule 19b–4(f)(6) thereunder.[7]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to modify IEX Rule 11.330(a)(2) to retire the IEX Data Platform data product (''Data Platform''). As discussed below, IEX is proposing to retire the Data Platform because IEX has determined that because IEX offers the same data in the Data Platform through other data products, the costs associated with maintaining and updating the Data Platform outweigh the benefits of offering the Data Platform.

IEX's Data Platform is both a human readable data feed available through IEX's website that offers aggregated top of book quotations for all displayed orders resting on IEX's Order Book[8] and last sale data (''TOPS Viewer''), and an application programming interface (the ''API'')[9] that offers aggregated top of book and depth of book quotations for all displayed orders resting on the Order Book at each price level as well as last sale data, each in near real time.[10] IEX understands that while both TOPS Viewer and the API provide potentially useful market data, because they are internet based they are subject to the concomitant latency associated therewith and are thus not generally utilized for time-sensitive trading decisions but for informational and research purposes. For example, by the time market data is viewed or obtained by query or update it will typically be stale and not usable for determining IEX's current protected quote, midpoint or available depth of book liquidity.

IEX provides all of the data available in TOPS Viewer and the API through other market data products. Specifically, IEX's ''TOPS''[11] feed contains all the data visible in the TOPS Viewer, and IEX's ''DEEP''[12] feed contains all the data accessible via the API. Additionally, IEX's ''HIST''[13] offers TOPS and DEEP data on a T+1 basis for download from the Exchange's public website.[14]

The TOPS and DEEP feeds also include additional information that is not included in the TOPS Viewer or API. Specifically, IEX recently introduced TOPS and DEEP ''snapshots'' that allow subscribers of those feeds to download point-in-time snapshots of TOPS or DEEP in order to enable them to accelerate late start recovery (*i.e.,* if a data subscriber's connection to the data feed is delayed or interrupted, the snapshot will provide the subscriber with point-in-time data that it can use to sync up its trading operations going forward).[15] In addition, IEX recently began disseminating a ''Retail Liquidity Indicator'' through both the TOPS and DEEP feeds, which is also distributed to the SIPs, but not to TOPS Viewer or the API.[16]

In view of the significant overlap in the data available in the Data Platform and in the TOPS and DEEP feeds, IEX has determined that the costs to maintain and update TOPS Viewer and the API are not warranted. IEX does not charge any fees to access either TOPS Viewer or the API, and thus has borne all costs for developing and supporting both data products. As with all businesses, IEX does not have unlimited resources and has determined that it is no longer in its commercial interests to incur costs to maintain and update TOPS Viewer and the API. Accordingly, IEX proposes to retire TOPS Viewer and the API, delete the current IEX Rule 11.330(a)(2), and renumber subparagraphs (a)(3)–(a)(5) to (a)(2)–(a)(4).

IEX also believes this proposed rule change will eliminate any possible confusion that may arise from a market participant trying to access data elements in TOPS Viewer and the API that can only be found in the TOPS and DEEP data products. Along those lines, in advance of issuing a formal trading alert as discussed below, IEX has been advising users of TOPS Viewer and the API that pending the filing and effectiveness of this rule change, IEX intends to retire both data products after November 18, 2021.[17]

Implementation

This proposed rule change is effective on filing, and the Exchange expects to implement it on November 19, 2021 (meaning November 18, 2021 will be the last day that TOPS Viewer and the API will be available to users), following the expiration of the 30-day operative delay. IEX will provide at least ten (10) days' notice to Members[18] and market participants of the implementation timeline.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5), in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposed rule change is consistent with the protection of investors and the public interest because it will continue to provide all market data currently available in TOPS Viewer and the API

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4.

[8] *See* IEX Rule 1.160(p).

[9] The IEX API enables a market participant to query IEX market data through a computer to computer based protocol. Through such queries, a market participant can obtain a series of static views of the IEX order book, or, can receive periodic updates to the top of book for a particular security.

[10] *See* IEX Rule 11.330(a)(2). The Data Platform would also include auction information (*see* IEX Rule 11.330(a)(2)) if there were any IEX-listed securities.

[11] *See* IEX Rule 11.330(a)(1).

[12] *See* IEX Rule 11.330(a)(3).

[13] *See* IEX Rule 11.330(a)(5).

[14] HIST data is available for download at *https://iextrading.com/trading/market-data/#hist-download.*

[15] *See* Trading Alert No. 2021–003, available at *https://iextrading.com/alerts/#/135* and Trading Alert No. 2021–031, available at *https://iextrading.com/alerts/#/163.*

[16] *See* Trading Alert 2021–036, *https://iextrading.com/alerts/#/169; see also,* Securities Exchange Act Release No. 92398 (July 13, 2021), 86 FR 38166 (July 19, 2021) (SR–IEX–2021–06).

[17] Notification is being provided via website headers on the TOPS Viewer and API pages of IEX's website, with a comparable header returned with any API queries, in order to notify API users that might not visit the website. The notifications also inform any users of the API that IEX's market data will continue to be available via the TOPS and DEEP feeds, as well as through third party vendors of IEX market data.

[18] *See* IEX Rule 1.160(s).

through the TOPS and DEEP feeds. IEX appreciates that retail investors and other non-professional market participants may not be able to utilize TOPS or DEEP in lieu of TOPS Viewer or the API. However, IEX understands that the market data available in TOPS Viewer and through the API is also available to retail investors and other non-professional market participants through brokerage accounts that must be maintained to enter orders on IEX.[19] Thus, the retirement of TOPS Viewer and the API will not adversely impact the ability of retail investors to access IEX market data when making investing decisions. Additionally, as discussed in the Purpose section, IEX's HIST data product allows anyone to download TOPS and DEEP data from IEX's public website on a T+1 basis, so the retirement of TOPS Viewer and the API will not adversely impact the ability of academics or other non-market participants to access historical IEX market data.

Additionally, IEX believes that retiring TOPS Viewer and the API will allow it to dedicate more resources to the maintenance of and enhancements to the TOPS and DEEP feeds. This reallocation of IEX's limited resources should serve to help remove impediments to a free and open market, in furtherance of the protection of investors and the public interest.

Finally, IEX notes that nothing in the Act requires IEX to provide a near real-time online version of its market data or any API with near real-time access to IEX's depth of book data product. No other exchange offers an online version or API that provides depth of book data analogous to the IEX API. One other exchange family, the Cboe exchanges, offers a similar, human readable, top of book viewer on its website free of charge.[20] The only other human readable top of book viewer offered by an exchange is offered by Nasdaq, which charges $76/month per professional subscriber and $15/month per non-professional subscriber to access the human readable top of book viewer.[21]

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the proposal is designed to enhance IEX's competitiveness with other markets by enabling IEX to focus its limited resources on the continued maintenance and enhancement of its TOPS and DEEP feeds. Nothing in this rule change will impact the ability of any other exchange to offer or not offer comparable market data products. Further, elimination of TOPS Viewer and the API will not adversely impact any equities exchanges or other competing venues of IEX since IEX will continue to provide its market data through the TOPS and DEEP feeds. In this regard, IEX does not believe that such exchanges and venues utilize either for other than informational purposes since their non-continuous nature is not well suited for operating a trading market. For example, by the time market data is viewed or obtained by query or update it will typically be stale and not usable for determining IEX's protected quote.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. All market participants will continue to be able to obtain IEX's market data through the TOPS and DEEP feeds, and as discussed in the Purpose section, there is more data available in the TOPS and DEEP feeds than in the TOPS Viewer and the API. Thus, this proposal will impact all market participants equally, any of which can obtain IEX market data through the TOPS and DEEP feeds, or through a third-party vendor.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[22] and Rule 19b–4(f)(6)[23] thereunder.

The Exchange has asked the Commission to waive the 30-day operative delay in order to discontinue the optional internet-based TOPS Viewer and API by November 18, 2021 because doing so: (1) Will allow developers to make code changes in advance of any year-end ''code freezes,'' and (2) would not adversely impact the ability of persons to access the same IEX market data.[24] The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Specifically, waiver of the operative delay will allow the Exchange to retire these optional market data products in a timely fashion well in advance of year-end code freezes and better focus its resources on its core market data feeds. In addition, according to the Exchange, the same and more IEX market data is available to market participants and others, through the Exchange's TOPS, DEEP and HIST data products. The proposal does not, therefore, present any novel issues and, accordingly, the Commission designates the proposal operative upon filing.[25]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[19] Only a Member may enter an order directly on IEX. Thus, retail investors and other market participants that are not Members must maintain an account with a Member of IEX in order to do so.

[20] *See https://www.cboe.com/us/equities/market_statistics/book_viewer/.*

[21] *See https://www.nasdaq.com/solutions/nasdaq-bookviewer#pricing.*

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2021–13 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–IEX–2021–13. This file number should be included in the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Section, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the IEX's principal office and on its internet website at *www.iextrading.com.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2021–13 and should be submitted on or before November 29, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24324 Filed 11–5–21; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93511]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Declaration of Effectiveness of the Fingerprint Plan of the Financial Industry Regulatory Authority, Inc.

November 2, 2021.

On October 28, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') a new fingerprint plan (''Plan'')[1] pursuant to Rule 17f–2(c)[2] under the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'').[3] The Plan supersedes and replaces FINRA's current fingerprint plan, which was declared effective for the Commission by the Division of Trading and Markets, pursuant to delegated authority, on May 2, 2006 (''FINRA's 2006 Plan'').[4]

FINRA states that it is adopting the Plan due to the age of FINRA's current fingerprint processing platform, and the availability of more modern alternatives offered by private vendors approved by the Federal Bureau of Investigation (''FBI'') to channel fingerprints.[5] Therefore, as discussed in more detail below, FINRA states that in order to continue to facilitate compliance with the fingerprinting requirement in Section 17(f)(2) of the Exchange Act, it is transitioning to a new fingerprinting process for broker-dealer personnel (of both FINRA members and other broker-dealers) and for FINRA personnel using the services of an FBI-approved channeler (''FBI-Approved Channel Partner'').[6] FINRA will continue at this time its current role as the channeler for processing fingerprints of transfer agent and clearing agency personnel that are submitted to FINRA.[7]

For the reasons discussed below, the Commission finds that, pursuant to Rule 17f–2(c) of the Exchange Act, the Plan is not inconsistent with the public interest and the protection of investors and, therefore, declares the Plan to be effective.

1. Applicable Standard

Section 17(f)(2) of the Act provides, in pertinent part, that every member of a national securities exchange, broker, dealer, registered transfer agent and registered clearing agency, and national securities association (as well as others), shall require that each of its partners, directors, officers, and employees be fingerprinted and shall submit such fingerprints, or cause the same to be submitted, to the Attorney General of the United States for identification and appropriate processing.[8] However, in accordance with Exchange Act Rule 17f–2(c), the fingerprinting requirement of Section 17(f)(2) may be satisfied by submitting appropriate and complete fingerprint cards to, among others, a registered national securities association (such as FINRA) which, pursuant to a plan filed with and declared effective by, the Commission, forwards such fingerprint cards to the Attorney General of the United States (''Attorney General'') or its designee for identification and appropriate processing.[9] Under Rule 17f–2(c), such fingerprinting plans—like FINRA's 2006 Plan and this Plan—shall not become effective unless it is declared effective

[1] Attached hereto as Exhibit A. *See also* Letter from Richard Pullano, Vice President and Associate General Counsel, FINRA, to Devin Ryan, Assistant Director, Office of Chief Counsel, Division of Trading and Markets, dated October 28, 2021 (''FINRA Letter''), available at *https://www.finra.org/sites/default/files/2021-11/fingerprint-plan.pdf.*

[2] 17 CFR 240.17f–2(c).

[3] 15 U.S.C. 78a *et seq.*

[4] *See* Exchange Act Release No. 53751 (May 2, 2006), 71 FR 27299 (May 10, 2006) (Declaration of Effectiveness of the Fingerprint Plan of the National Association of Securities Dealers, Inc.). FINRA will continue to channel fingerprints for these personnel consistent with the 2006 Fingerprint Plan until the new fingerprinting process set forth in the Plan is fully implemented.

[5] *See* FINRA Letter at 1.

[6] *See also infra* Section 2. The FBI-Approved Channel Partner is one of a limited number of entities approved by the FBI to submit fingerprints to the FBI and receive the results on behalf of an organization using that information for authorized non-criminal justice purposes (*e.g.,* employment suitability, licensing determinations, etc.). The FBI reviews and approves all outsourced channeling relationships consistent with its outsourcing standards and protocols. As outlined in the September 28, 2021 letter from the FBI's National Crime Prevention and Privacy Compact Council Office (''CCO Letter''), the FBI has reviewed and conditionally granted permission to FINRA to use a specified FBI-Approved Channel Partner contingent upon FINRA filing a fingerprint plan with the Commission and the Commission declaring that fingerprint plan effective. *See* FINRA Letter at 2, n.4 (discussing the CCO Letter, available at *https://www.finra.org/sites/default/files/2021-11/fingerprint-plan.pdf*). The terms of the CCO Letter are incorporated by reference in the Plan. *See* Exhibit A at 1, n. 3.

[7] *See also infra* Section 3. FINRA notes that it is seeking to identify an alternative approach that would enable transfer agents and clearing agencies to efficiently fulfill their obligations to fingerprint their personnel, but would not involve FINRA acting in a channeler role. FINRA notes that, for the last two years, transfer agent and clearing agency personnel have accounted for less than two percent of the fingerprints processed by FINRA. FINRA intends to work with the Commission, FBI and the transfer agent and clearing agency communities to identify this alternative approach. *See* FINRA Letter at 1.

[8] 15 U.S.C. 78q(f)(2).

[9] 17 CFR 240.17f–2(c).

by the Commission, which requires the Commission to find that the plan is ''not inconsistent with the public interest or the protection of investors.'' [10]

FINRA states that the purpose of the Plan is to facilitate compliance with Section 17(f)(2) of the Act and Rule 17f–2 thereunder by providing a program for FINRA members,[11] other broker-dealers, transfer agents, clearing agencies and FINRA to have the fingerprints of their partners, directors, officers, and employees processed by the Attorney General.[12]

2. FINRA Members and Other Broker-Dealers

Under FINRA's 2006 Plan, FINRA accepts fingerprints and identifying information from member firms and other securities industry participants required to be fingerprinted under Rule 17f–2.[13] FINRA then transmits these fingerprints and identifying information to the FBI, which the Attorney General has designated to identify and process such fingerprints, consistent with protocols and requirements established by the Attorney General.[14] However, as set forth in the Plan, FINRA is partnering with an FBI-Approved Channel Partner to process fingerprints and other identifying information from personnel of FINRA members and other broker-dealers required to be fingerprinted pursuant to Section 17(f)(2).[15] Under the Plan, FINRA members or other broker-dealers will work with the FBI-Approved Channel Partner to fingerprint such personnel or accept fingerprints from such personnel (either in electronic or hard copy format), and the FBI-Approved Channel Partner will submit such fingerprints to the Attorney General for processing consistent with the protocols and requirements established by the Attorney General.[16] The FBI-Approved Channel Partner will offer state-of-the-art fingerprint services to broker-dealers that include collecting fingerprints at locations nationwide and leasing fingerprint equipment to broker-dealers that wish to fingerprint personnel in-house.[17]

Also under the terms of the Plan, at least the following three key aspects of FINRA's 2006 Plan will remain unchanged.[18] First, FINRA will continue to receive results after the fingerprints have been processed by the Attorney General and FINRA will continue to make those results available to authorized recipients (*i.e.,* to a member or other broker-dealer that submitted the fingerprints and to regulators, as appropriate, for licensing, registration and other regulatory purposes), consistent with protocols and requirements established by the Attorney General.[19] Second, members and other broker-dealers will continue to be able to view the status and results of the processed fingerprints, including any relevant criminal history information, through FINRA systems.[20] Third, FINRA will continue to review the fingerprint results to fulfill its regulatory responsibilities, store those results in the CRD or FPRD systems and make them available to other regulators that are authorized to view the results.[21]

3. Transfer Agents and Clearing Agencies

Under the Plan, FINRA, rather than the FBI-Approved Channel Partner discussed above, will continue to use its current fingerprint processing platform to accept fingerprints and identifying information from transfer agent and clearing agency personnel who are required to be fingerprinted pursuant to Rule 17f–2 and who submit fingerprints to FINRA for processing.[22] FINRA will also continue to transmit fingerprints from such personnel to the Attorney General for identification and processing consistent with protocols and requirements established by the Attorney General.[23]

4. FINRA Personnel

The FBI-Approved Channel Partner will also process fingerprints and identifying information from FINRA personnel who are required to be fingerprinted under Section 17(f)(2) of the Act and consistent with its Policy to Conduct Fingerprint-Based Background Checks (''Fingerprint Policy'').[24] The FBI-Approved Channel Partner will also transmit these fingerprints and identifying information to the Attorney General for identification and processing consistent with protocols and requirements established by the Attorney General and securely make the results available to FINRA after the fingerprints have been processed.[25] FINRA will evaluate such results and take any appropriate action in accordance with the terms of its Fingerprint Policy.[26]

5. Commission's Declaration of Effectiveness of the Plan

In accordance with Rule 17f–2(c) of the Act, the Commission has reviewed the procedures detailed in the Plan and believes that the Plan is not inconsistent with the public interest and the protection of investors.

The Commission observes that most of FINRA's 2006 Plan, which the Commission found previously to be consistent with the public interest and the protection of investors,[27] will remain largely unchanged.[28] As a result, the Commission has no reason to revisit its prior finding with respect to those unchanged provisions.

With respect to FINRA's decision to partner with a new FBI-Approved

[10] *See id.* The Commission may also impose any terms and conditions relating to the provisions of the plan and the period of its effectiveness as it may deem necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. *See id.*

[11] For purposes of the Plan, the term ''members'' included Capital Acquisition Brokers, Funding Portals and applicants for FINRA membership.

[12] *See* Exhibit A.

[13] *See* FINRA Letter at 1, n. 2. FINRA's current platform uses a customized application that include software licensed from a vendor, and specialized equipment (to scan, digitize and transmit fingerprints in accordance with FBI requirements). The vendor has discontinued the software used in the customized application and ceased providing support for it in July 2021. As a result, the customized application, while still fully operational, is currently supported only by FINRA technology resources. *See* id. at 1.

[14] *See supra* note 4, 71 FR at 27299–300.

[15] *See* Exhibit A at 1.

[16] *See id.*

[17] *See* FINRA Letter at 2.

[18] *See id.* at 2–3. *See also* Exhibit A at 2.

[19] *See* Exhibit A at 2.

[20] These systems include the Central Registration Depository (''CRD'') and the Funding Portal Registration Depository (''FPRD''). *See* Exhibit A at 2.

[21] FINRA explains that it reviews fingerprint results to ensure that applicants for registration have reported appropriately information responsive to the questions on Form U4 (the Uniform Application for Securities Industry Registration or Transfer) relating to criminal history and to identify whether any broker-dealer personnel required to be fingerprinted is subject to a statutory disqualification under the Exchange Act based upon a criminal conviction. *See* FINRA Letter at 3.

[22] *See* FINRA Letter at 3.

[23] FINRA also explains that, because transfer agents and clearing agencies do not use the CRD system for registration purposes, FINRA is unable to disseminate the fingerprint statuses and results through that system (as it does for broker-dealer personnel). *See* FINRA Letter at 3.

[24] Securities Exchange Act Release No. 50157 (August 5, 2004), 69 FR 49924 (August 12, 2004) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2004–095). *See* Exhibit A at 3.

[25] *See id.*

[26] *See id.*

[27] *See supra* note 4 and accompanying text.

[28] For example, and as discussed above in section 2, at least three key aspects of FINRA's 2006 Plan will remain unchanged for FINRA members and other broker-dealers. *See supra* note 18 and accompanying text. FINRA also states that its customized application for processing fingerprints will remain fully operational, although it will be supported only by FINRA technology resources. *See* FINRA Letter at 1, n. 1. With respect to transfer agent and clearing agent personnel, the Plan simply memorializes FINRA's existing procedures for processing fingerprints and other identifying information for these personnel who are required to be fingerprinted pursuant to Section 17(f)(2). *See id.* at 3–4.

Channel Partner[29] to be the central point of intake and to process fingerprints and identifying information from its members, other broker-dealers and FINRA personnel, rather than doing so itself, the Commission observes the following representations made by FINRA. FINRA states that the FBI-Approved Channel Partner will offer state-of-the-art fingerprint services that include collecting fingerprints at locations nationwide and leasing fingerprint equipment to broker-dealers that wish to print personnel in-house.[30] Notably, FINRA believes that the partnership with the FBI-Approved Channel Partner will enable FINRA to continue to reliably facilitate fingerprinting of the personnel of broker-dealers as required under Section 17(f)(2) of the Exchange Act.[31] FINRA also believes this partnership will enable FINRA to continue to fulfill its critical regulatory and investor protection responsibilities, including the identification of broker-dealer personnel required to be fingerprinted who may be subject to a statutory disqualification based on a criminal conviction.[32] Similarly, FINRA states that the partnership will enable it to continue to fulfill its Exchange Act requirement to perform fingerprint-based background checks on covered FINRA personnel.[33]

The Commission agrees with FINRA that these statutorily-mandated fingerprint-based background checks—whether performed by FINRA itself under the 2006 Plan or by an FBI-Approved Channel Partner under this Plan—will continue to help protect investors and serve the public interest. Based on the foregoing, the Commission finds that, pursuant to Rule 17f–2(c) of the Exchange Act, the Plan is not inconsistent with the public interest and the protection of investors and, therefore, declares the Plan to be effective.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

Exhibit A

Financial Industry Regulatory Authority; Fingerprint Plan

The Financial Industry Regulatory Authority, Inc. (''FINRA'') submits this fingerprint plan (''Plan'') pursuant to Rule 17f–2(c) under the Securities Exchange Act of 1934 (''Exchange Act''). This Plan supersedes and replaces FINRA's current fingerprint plan, which was declared effective by the Securities and Exchange Commission (''Commission'') on May 2, 2006 (the ''2006 Fingerprint Plan'').[35]

The purpose of this Plan is to facilitate compliance with Section 17(f)(2) of the Exchange Act by providing a program for FINRA members,[36] other broker-dealers, transfer agents, clearing agencies, and FINRA to have the fingerprints of their partners, directors, officers, and employees processed by the Attorney General of the United States or its designee (hereinafter ''Attorney General'').

1. Members and Other Broker-Dealers

FINRA is partnering with an FBI-approved private channeler (''FBI-Approved Channel Partner'')[37] to process fingerprints and identifying information from personnel of members and other broker-dealers required to be fingerprinted pursuant to Exchange Act Section 17(f)(2) and Rule 17f–2 thereunder. The FBI-Approved Channel Partner fingerprints such personnel or accepts fingerprints of such personnel (either in electronic or hard copy format) and submits such fingerprints to the Attorney General for processing consistent with protocols and requirements established by the Attorney General.[38]

FINRA receives results from the FBI-Approved Channel Partner after the fingerprints have been processed by the Attorney General and makes those results available to authorized recipients (*i.e.,* to a member or other broker-dealer that submitted the fingerprints and to regulators, as appropriate, for licensing, registration and other regulatory purposes), consistent with protocols and requirements established by the Attorney General. With respect to members and other broker-dealers, FINRA also reviews any Criminal History Record Information returned by the Attorney General to identify persons who may be subject to statutory disqualification under the Exchange Act and to take action, as appropriate, with respect to such persons.

FINRA maintains copies of fingerprint processing results received from the Attorney General with respect to fingerprints submitted by the FBI-Approved Channel Partner pursuant to this Plan in accordance with FINRA's records policy.[39] Any maintenance of fingerprint records by FINRA shall be for FINRA's own administrative purposes; FINRA is not undertaking to maintain fingerprint records on behalf of FINRA members pursuant to Exchange Act Rule 17f–2(d)(2). FINRA records in FINRA systems the status of fingerprints of personnel of members and other broker-dealers submitted to the Attorney General.[40] Through these systems, FINRA makes available to a member or other broker-dealer that has submitted fingerprints the status and results of such fingerprints after submission to the Attorney General.

[29] *See supra* note 6 (discussing the FBI's conditional approval of FINRA using a specified FBI-Approved Channel Partner). *See also* Exhibit A at 1, n. 3.

[30] *See* FINRA Letter at 2.

[31] *See id* at 4.

[32] *See id.*

[33] *See id.*

[34] 17 CFR 200.30–3(a)(17)(iii).

[35] Securities Exchange Act Release No. 53751 (May 2, 2006), 71 FR 27299 (May 10, 2006) (Declaration of Effectiveness of the Fingerprint Plan of the National Association of Securities Dealers, Inc.). Pursuant to the 2006 Fingerprint Plan, FINRA channels fingerprints for, among others, FINRA members, other broker-dealers and FINRA personnel. FINRA will continue to channel fingerprints for these personnel consistent with the 2006 Fingerprint Plan until the new fingerprinting process set forth in the Plan is fully implemented.

[36] For purposes of the Plan, the term ''members'' includes Capital Acquisition Brokers, Funding Portals and applicants for FINRA membership.

[37] The FBI-Approved Channel Partner is one of a limited number of entities approved by the FBI to submit fingerprints to the FBI and receive the results on behalf of an organization using that information for authorized non-criminal justice purposes (*e.g.,* employment suitability, licensing determinations, etc.). The FBI reviews and approves all outsourced channeling relationships consistent with its outsourcing standards and protocols. As outlined in the September 28, 2021 letter from the FBI's National Crime Prevention and Privacy Compact Council Office (''CCO Letter''), the FBI has reviewed and conditionally granted permission to FINRA to use a specified FBI-Approved Channel Partner contingent upon FINRA filing a fingerprint plan with the Commission and the Commission declaring that fingerprint plan effective. *See* CCO Letter, available at *https://www.finra.org/registration-exams-ce/classic-crd/fingerprints.* The terms of the CCO Letter are incorporated by reference in the Plan.

[38] On its website, FINRA informs its members and other broker-dealers of the availability of fingerprint services and any fees charged by FINRA in connection with those services and the processing of fingerprints pursuant to this Plan. *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints.*

[39] FINRA's records policy is to maintain all records for at least five years.

[40] These systems include the Central Registration Depository (CRD®) and the Funding Portal Registration Depository (FPRD®).

2. Transfer Agents and Clearing Agencies

FINRA accepts fingerprints and identifying information from transfer agent personnel and clearing agency personnel who are required to be fingerprinted pursuant to Exchange Act Section 17(f)(2) and Rule 17f–2 thereunder. FINRA accepts fingerprints of such personnel in hard copy format and transmits fingerprints to the Attorney General for identification and processing consistent with protocols and requirements established by the Attorney General.[41] After receiving the processed results, FINRA transmits them to the submitting transfer agent or clearing agency (*i.e.,* an authorized recipient of the results). FINRA informs transfer agents and clearing agencies of its fingerprint processing services and the fees associated with those services.

3. FINRA Personnel

FINRA partners with the FBI-Approved Channel Partner to obtain fingerprints and identifying information from FINRA personnel who are required to be fingerprinted under Exchange Act Section 17(f)(2) and consistent with its Policy to Conduct Fingerprint-Based Background Checks (''Fingerprint Policy'').[42] The FBI-Approved Channel Partner transmits fingerprints to the Attorney General for identification and processing consistent with protocols and requirements established by the Attorney General and securely makes the results available to FINRA after the fingerprints have been processed. FINRA evaluates the fingerprint results and takes any appropriate action in accordance with the terms of the Fingerprint Policy.

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[41] FINRA is channeling transfer agent and clearing agency fingerprints and not using the FBI-Approved Channel Partner for this purpose.

[42] Securities Exchange Act Release No. 50157 (August 5, 2004), 69 FR 49924 (August 12, 2004) (Notice of Filing and Immediate Effectiveness of File No. SR–NASD–2004–095).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93504; File No. SR–NYSEArca–2021–90]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of Grayscale Bitcoin Trust (BTC) Under NYSE Arca Rule 8.201–E

November 2, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 19, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, 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 list and trade shares of the following under NYSE Arca Rule 8.201–E: Grayscale Bitcoin Trust (BTC) (the ''Trust'').[4] The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Trust was previously named Bitcoin Investment Trust, whose name was changed pursuant to a Certificate of Amendment to the Certificate of Trust of Bitcoin Investment Trust filed with the Delaware Secretary of State on January 11, 2019.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Under NYSE Arca Rule 8.201–E, the Exchange may propose to list and/or trade pursuant to unlisted trading privileges ''Commodity-Based Trust Shares.'' [5] The Exchange proposes to list and trade shares (''Shares'') [6] of the Trust pursuant to NYSE Arca Rule 8.201–E.[7]

[5] Commodity-Based Trust Shares are securities issued by a trust that represent investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the Trust.

[6] The Shares are expected to be listed under the ticker symbol ''BTC.''

[7] On March 22, 2016, the Trust confidentially filed its draft registration statement on Form 10 under the Securities Act of 1933 (15 U.S.C. 77a) (the ''Securities Act'') (File No. 377–01289) (the ''Draft Registration Statement on Form S–1''). On May 31, 2016, the Trust confidentially filed Amendment No. 1 to the Draft Registration Statement on Form S–1. On July 29, 2016, the Trust confidentially filed Amendment No. 2 to the Draft Registration Statement on Form S–1. On November 2, 2016, the Trust confidentially filed Amendment No. 3 to the Draft Registration Statement on Form S–1. The Jumpstart Our Business Startups Act (the ''JOBS Act''), enacted on April 5, 2012, added Section 6(e) to the Securities Act. Section 6(e) of the Securities Act provides that an ''emerging growth company'' may confidentially submit to the Commission a draft registration statement for confidential, non-public review by the Commission staff prior to public filing, provided that the initial confidential submission and all amendments thereto shall be publicly filed not later than 21 days before the date on which the issuer conducts a road show, as such term is defined in Securities Act Rule 433(h)(4). An emerging growth company is defined in Section 2(a)(19) of the Securities Act as an issuer with less than $1,000,000,000 total annual gross revenues during its most recently completed fiscal year. The Trust meets the definition of an emerging growth company and consequently submitted its Draft Registration Statement on Form S–1 to the Commission on a confidential basis.

On January 20, 2017, the Trust filed its registration statement on Form S–1 under the Securities Act (File No. 333–215627) (the ''Registration Statement on Form S–1''). On March 24, 2017, the Trust filed Amendment No. 1 to the Registration Statement on Form S–1. On May 4, 2017, the Trust filed Amendment No. 2 to the Registration Statement on Form S–1. On October 25, 2017, the Trust requested the withdrawal of the Registration Statement on Form S–1.

On October 3, 2018, the Trust confidentially filed its draft registration statement on Form 10 under the Securities Act (File No. 377–02297) (the ''Draft Registration Statement on Form 10''). On December 6, 2018, the Trust confidentially filed Amendment No. 1 to the Draft Registration Statement on Form 10. On February 25, 2019 the Trust confidentially filed Amendment No. 2 to the Draft Registration Statement on Form 10. On April 15, 2019, the Trust confidentially filed Amendment No. 3 to the Draft Registration Statement on Form 10. On September 9, 2019, the Trust confidentially filed Amendment No. 4 to the Draft Registration Statement on Form 10. As noted above, the Trust meets the definition of an emerging growth company under the JOBS Act and consequently submitted its Draft Registration Statement on Form 10 to the Commission on a confidential basis.

The sponsor of the Trust is Grayscale Investments, LLC (''Sponsor''), a Delaware limited liability company. The Sponsor is a wholly-owned subsidiary of Digital Currency Group, Inc. (''Digital Currency Group''). The trustee for the Trust is Delaware Trust Company (''Trustee''). The custodian for the Trust is Coinbase Custody Trust Company, LLC (''Custodian'').[8] The distribution and marketing agent for the Trust is Genesis. The index provider for the Trust is TradeBlock, Inc. (the ''Index Provider'').

The Trust is a Delaware statutory trust, organized on September 13, 2013, that operates pursuant to a trust agreement between the Sponsor and the Trustee (''Trust Agreement''). The Trust has no fixed termination date.

Operation of the Trust

According to the Annual Report, the Trust's assets consist solely of Bitcoins, Incidental Rights,[9] IR Virtual Currency,[10] proceeds from the sale of Bitcoins, Incidental Rights, and IR Virtual Currency pending use of such cash for payment of Additional Trust Expenses [11] or distribution to shareholders, and any rights of the Trust pursuant to any agreements, other than the Trust Agreement, to which the Trust is a party. Each Share represents a proportional interest, based on the total number of Shares outstanding, in each of the Trust's assets as determined by reference to the Index Price,[12] less the Trust's expenses and other liabilities (which include accrued but unpaid fees and expenses). The Sponsor expects that the market price of the Shares will fluctuate over time in response to the market prices of Bitcoin. In addition, because the Shares reflect the estimated accrued but unpaid expenses of the Trust, the number of Bitcoins represented by a Share will gradually decrease over time as the Trust's Bitcoins are used to pay the Trust's expenses. The Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for purposes of determining the Trust's ''Digital Asset Holdings'' (as described below) or the Digital Asset Holdings per Share.

The activities of the Trust are limited to (i) issuing ''Baskets'' (as defined below) in exchange for Bitcoins transferred to the Trust as consideration in connection with the creations, (ii) transferring or selling Bitcoins, Incidental Rights, and IR Virtual Currency as necessary to cover the ''Sponsor's Fee'' and/or certain Trust expenses, (iii) transferring Bitcoins in exchange for Baskets surrendered for redemption (subject to obtaining regulatory approval from the SEC and approval of the Sponsor), (iv) causing the Sponsor to sell Bitcoins, Incidental Rights, and IR Virtual Currency on the termination of the Trust, (v) making distributions of Incidental Rights and/or IR Virtual Currency or cash from the sale thereof, and (vi) engaging in all administrative and security procedures necessary to accomplish such activities in accordance with the provisions of the Trust Agreement, the Custodian Agreement, the Index License Agreement and the Participant Agreements.

In addition, the Trust may engage in any lawful activity necessary or desirable in order to facilitate shareholders' access to Incidental Rights or IR Virtual Currency, provided that such activities do not conflict with the terms of the Trust Agreement. The Trust will not be actively managed. It will not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the market prices of Bitcoins.

Investment Objective

According to the Annual Report, and as further described below, the Trust's investment objective is for the value of the Shares (based on Bitcoin per Share) to reflect the value of the Bitcoins held by the Trust, as determined by reference to the Index Price, less the Trust's expenses and other liabilities. While an investment in the Shares is not a direct investment in Bitcoin, the Shares are designed to provide investors with a cost-effective and convenient way to gain investment exposure to Bitcoin. A substantial direct investment in Bitcoin may require expensive and sometimes complicated arrangements in connection with the acquisition, security and safekeeping of the Bitcoin and may involve the payment of substantial fees to acquire such Bitcoin

On November 19, 2019, the Trust filed its registration statement on Form 10 under the Securities Act (File No. 000–56121) (the ''Registration Statement on Form 10''). On December 31, 2019, the Trust filed Amendment No. 1 to the Registration Statement on Form 10. On January 21, 2020, the Registration Statement on Form 10 was automatically deemed effective.

On March 20, 2020, the Trust filed its annual report on Form 10–K under the Securities Act (File No. 000–56121). On May 8, 2020, August 7, 2020 and November 6, 2020, the Trust filed its quarterly reports on Form 10–Q under the Securities Act (File No. 000–56121). On March 5, 2021, the Trust filed its annual report on Form 10–K under the Securities Act (File No. 000–56121) (the ''Annual Report''). On May 7, 2021 and August 6, 2021, the Trust filed its quarterly reports on Form 10–Q under the Securities Act (File No. 000–56121) (the ''Quarterly Reports''). The descriptions of the Trust, the Shares, and Bitcoin contained herein are based, in part, on the Annual Report and Quarterly Reports.

On January 17, 2019, the Trust submitted to the Commission an amended Form D as a business trust. Shares of the Trust have been quoted on OTC Market's OTCQX Best Marketplace under the symbol ''GBTC'' since March 26, 2015. On February 22, 2019 and March 20, 2020, the Trust published annual reports for GBTC for the periods ended December 31, 2018 and December 31, 2019, respectively. On May 14, 2019, August 8, 2019, November 14, 2019, May 8, 2020, August 7, 2020 and November 6, 2020, the Trust published quarterly reports for GBTC for the periods ended March 31, 2019, June 30, 2019, September 30, 2019, March 31, 2020, June 30, 2020 and September 30, 2020 respectively. Reports published before January 11, 2020, the date on which the Trust's Shares became registered pursuant to Section 12(g) of the Act, can be found on OTC Market's website (*http://www.otcmarkets.com/stock/GBTC/disclosure*), and reports published on or after January 11, 2020 can be found on OTC Market's website (*http://www.otcmarkets.com/stock/GBTC/disclosure*) and the Commission's website (*https://www.sec.gov/cgi-bin/browse-edgar?CIK=gbtc&owner=exclude&action=getcompany*). The Shares will be of the same class and will have the same rights as shares of GBTC. Effective October 28, 2014, the Trust suspended its redemption program for shares of GBTC, in which shareholders were permitted to request the redemption of their shares through Genesis Global Trading, Inc. (formerly known as SecondMarket, Inc.), an affiliate of the Sponsor and the Trust (''Genesis''). According to the Sponsor, freely tradeable shares of GBTC will remain freely tradeable Shares on the date of the listing of the Shares that are unregistered under the Securities Act. Restricted shares of GBTC will remain subject to private placement restrictions and the holders of such restricted shares will continue to hold those Shares subject to those restrictions until they become freely tradable Shares.

[8] According to the Annual Report, Digital Currency Group owns a minority interest in Coinbase, Inc., which is the parent company of the Custodian, representing less than 1.0% of its equity.

[9] ''Incidental Rights'' are rights to acquire, or otherwise establish dominion and control over, any virtual currency or other asset or right, which rights are incident to the Trust's ownership of Bitcoins and arise without any action of the Trust, or of the Sponsor or Trustee on behalf of the Trust.

[10] ''IR Virtual Currency'' is any virtual currency tokens, or other asset or right, acquired by the Trust through the exercise (subject to the applicable provisions of the Trust Agreement) of any Incidental Right.

[11] ''Additional Trust Expenses'' are any expenses incurred by the Trust in addition to the Sponsor's Fee that are not Sponsor-paid Expenses, including, but not limited to, (i) taxes and governmental charges, (ii) expenses and costs of any extraordinary services performed by the Sponsor (or any other service provider) on behalf of the Trust to protect the Trust or the interests of shareholders (including in connection with any Incidental Rights and any IR Virtual Currency), (iii) any indemnification of the Custodian or other agents, service providers or counterparties of the Trust, (iv) the fees and expenses related to the listing, quotation or trading of the Shares on any Secondary Market (including legal, marketing and audit fees and expenses) to the extent exceeding $600,000 in any given fiscal year and (v) extraordinary legal fees and expenses, including any legal fees and expenses incurred in connection with litigation, regulatory enforcement or investigation matters.

[12] The ''Index Price'' means the U.S. dollar value of a Bitcoin derived from the Digital Asset Exchanges that are reflected in the Index, calculated at 4:00 p.m., New York time, on each business day. For purposes of the Trust Agreement, the term Bitcoin Index Price has the same meaning as the Index Price as defined herein.

from third-party facilitators through cash payments of U.S. dollars. Because the value of the Shares is correlated with the value of Bitcoin held by the Trust, it is important to understand the investment attributes of, and the market for, Bitcoin.

Bitcoin and the Bitcoin Network

According to the Annual Report, Bitcoin is a digital asset that is created and transmitted through the operations of the peer-to-peer ''Bitcoin Network,'' a decentralized network of computers that operates on cryptographic protocols. No single entity owns or operates the Bitcoin Network, the infrastructure of which is collectively maintained by a decentralized user base. The Bitcoin Network allows people to exchange tokens of value, called Bitcoin, which are recorded on a public transaction ledger known as a Blockchain. Bitcoin can be used to pay for goods and services, or it can be converted to fiat currencies, such as the U.S. dollar, at rates determined on ''Digital Asset Markets'' [13] that trade Bitcoin or in individual end-user-to-end-user transactions under a barter system.

The Bitcoin Network is decentralized and does not require governmental authorities or financial institution intermediaries to create, transmit, or determine the value of Bitcoin. Rather, Bitcoin is created and allocated by the Bitcoin Network protocol through a ''mining'' process. The value of Bitcoin is determined by the supply of and demand for Bitcoin on the Digital Asset Markets or in private end-user-to-end-user transactions.

New Bitcoin are created and rewarded to the miners of a block in the Blockchain for verifying transactions. The Blockchain is effectively a decentralized database that includes all blocks that have been solved by miners, and it is updated to include new blocks as they are solved. Each Bitcoin transaction is broadcast to the Bitcoin Network and, when included in a block, recorded in the Blockchain. As each new block records outstanding Bitcoin transactions, and outstanding transactions are settled and validated through such recording, the Blockchain represents a complete, transparent and unbroken history of all transactions of the Bitcoin Network.

Summary of a Bitcoin Transaction

Prior to engaging in Bitcoin transactions directly on the Bitcoin Network, a user generally must first install on its computer or mobile device a Bitcoin Network software program that will allow the user to generate a private and public key pair associated with a Bitcoin address, commonly referred to as a ''wallet.'' The Bitcoin Network software program and the Bitcoin address also enable the user to connect to the Bitcoin Network and transfer Bitcoin to, and receive Bitcoin from, other users.

Each Bitcoin Network address, or wallet, is associated with a unique ''public key'' and ''private key'' pair. To receive Bitcoin, the Bitcoin recipient must provide its public key to the party initiating the transfer. This activity is analogous to a recipient for a transaction in U.S. dollars providing a routing address in wire instructions to the payor so that cash may be wired to the recipient's account. The payor approves the transfer to the address provided by the recipient by ''signing'' a transaction that consists of the recipient's public key with the private key of the address from where the payor is transferring the Bitcoin. The recipient, however, does not make public or provide to the sender its related private key.

Neither the recipient nor the sender reveal their private keys in a transaction, because the private key authorizes transfer of the funds in that address to other users. Therefore, if a user loses his private key, the user may permanently lose access to the Bitcoin contained in the associated address. Likewise, Bitcoin is irretrievably lost if the private key associated with them is deleted and no backup has been made. When sending Bitcoin, a user's Bitcoin Network software program must validate the transaction with the associated private key. In addition, since every computation on the Bitcoin Network requires processing power, there is a transaction fee involved with the transfer that is paid by the payor. The resulting digitally validated transaction is sent by the user's Bitcoin Network software program to the Bitcoin Network miners to allow transaction confirmation.

Bitcoin Network miners record and confirm transactions when they mine and add blocks of information to the Blockchain. When a miner mines a block, it creates that block, which includes data relating to (i) the satisfaction of the consensus mechanism to mine the block, (ii) a reference to the prior block in the Blockchain to which the new block is being added and (iii) transactions that have submitted to the Bitcoin Network but have not yet been added to the Blockchain. The miner becomes aware of outstanding, unrecorded transactions through the data packet transmission and distribution discussed above.

Upon the addition of a block included in the Blockchain, the Bitcoin Network software program of both the spending party and the receiving party will show confirmation of the transaction on the Blockchain and reflect an adjustment to the Bitcoin balance in each party's Bitcoin Network public key, completing the Bitcoin transaction. Once a transaction is confirmed on the Blockchain, it is irreversible.

Some Bitcoin transactions are conducted ''off-blockchain'' and are therefore not recorded in the Blockchain. Some ''off-blockchain transactions'' involve the transfer of control over, or ownership of, a specific digital wallet holding Bitcoin or the reallocation of ownership of certain Bitcoin in a pooled-ownership digital wallet, such as a digital wallet owned by a Digital Asset Exchange. In contrast to on-blockchain transactions, which are publicly recorded on the Blockchain, information and data regarding off-blockchain transactions are generally not publicly available. Therefore, off-blockchain transactions are not truly Bitcoin transactions in that they do not involve the transfer of transaction data on the Bitcoin Network and do not reflect a movement of Bitcoin between addresses recorded in the Blockchain. For these reasons, off-blockchain transactions are subject to risks, as any such transfer of Bitcoin ownership is not protected by the protocol behind the Bitcoin Network or recorded in, and validated through, the blockchain mechanism.

Custody of the Trust's Bitcoins

Digital assets and digital asset transactions are recorded and validated on blockchains, the public transaction ledgers of a digital asset network. Each digital asset blockchain serves as a record of ownership for all of the units of such digital asset, even in the case of certain privacy-focused digital assets, where the transactions themselves are not publicly viewable. All digital assets recorded on a blockchain are associated with a public blockchain address, also referred to as a digital wallet. Digital assets held at a particular public blockchain address may be accessed and

[13] A ''Digital Asset Market'' is a ''Brokered Market,'' ''Dealer Market,'' ''Principal-to-Principal Market'' or ''Exchange Market,'' as each such term is defined in the Financial Accounting Standards Board Accounting Standards Codification Master Glossary. The ''Digital Asset Exchange Market'' is the global exchange market for the trading of Bitcoins, which consists of transactions on electronic Digital Asset Exchanges. A ''Digital Asset Exchange'' is an electronic marketplace where exchange participants may trade, buy and sell Bitcoins based on bid-ask trading. The largest Digital Asset Exchanges are online and typically trade on a 24-hour basis, publishing transaction price and volume data.

transferred using a corresponding private key.

Key Generation

Public addresses and their corresponding private keys are generated by the Custodian in secret key generation ceremonies at secure locations inside faraday cages, which are enclosures used to block electromagnetic fields and mitigate attacks. The Custodian uses quantum random number generators to generate the public and private key pairs.

Once generated, private keys are encrypted, separated into ''shards,'' and then further encrypted. After the key generation ceremony, all materials used to generate private keys, including computers, are destroyed. All key generation ceremonies are performed offline. No party other than the Custodian has access to the private key shards of the Trust.

Key Storage

Private key shards are distributed geographically in secure vaults around the world, including in the United States. The locations of the secure vaults may change regularly and are kept confidential by the Custodian for security purposes.

The Digital Asset Account [14] uses offline storage, or ''cold storage'', mechanisms to secure the Trust's private keys. The term cold storage refers to a safeguarding method by which the private keys corresponding to digital assets are disconnected and/or deleted entirely from the internet. Cold storage of private keys may involve keeping such keys on a non-networked (or ''airgapped'') computer or electronic device or storing the private keys on a storage device (for example, a USB thumb drive) or printed medium (for example, papyrus, paper, or a metallic object). A digital wallet may receive deposits of digital assets but may not send digital assets without use of the digital assets' corresponding private keys. In order to send digital assets from a digital wallet in which the private keys are kept in cold storage, either the private keys must be retrieved from cold storage and entered into an online, or ''hot,'' digital asset software program to sign the transaction, or the unsigned transaction must be transferred to the cold server in which the private keys are held for signature by the private keys and then transferred back to the online digital asset software program. At that point, the user of the digital wallet can transfer its digital assets.

Security Procedures

The Custodian is the custodian of the Trust's private keys in accordance with the terms and provisions of the Custodian Agreement. Transfers from the Digital Asset Account require certain security procedures, including, but not limited to, multiple encrypted private key shards, usernames, passwords and 2-step verification. Multiple private key shards held by the Custodian must be combined to reconstitute the private key to sign any transaction in order to transfer the Trust's assets. Private key shards are distributed geographically in secure vaults around the world, including in the United States.

As a result, if any one secure vault is ever compromised, this event will have no impact on the ability of the Trust to access its assets, other than a possible delay in operations, while one or more of the other secure vaults is used instead. These security procedures are intended to remove single points of failure in the protection of the Trust's assets.

Transfers of Bitcoins to the Digital Asset Account will be available to the Trust once processed on the Blockchain.

Subject to obtaining regulatory approval to operate a redemption program and authorization of the Sponsor, the process of accessing and withdrawing Bitcoin from the Trust to redeem a Basket by an Authorized Participant will follow the same general procedure as transferring Bitcoins to the Trust to create a Basket by an Authorized Participant, only in reverse.

Digital Asset Holdings

According to the Annual Report, the Trust's assets consist solely of Bitcoins, Incidental Rights, IR Virtual Currency, proceeds from the sale of Bitcoins, Incidental Rights, and IR Virtual Currency pending use of such cash for payment of Additional Trust Expenses or distribution to the shareholders, and any rights of the Trust pursuant to any agreements, other than the Trust Agreement, to which the Trust is a party. Each Share represents a proportional interest, based on the total number of Shares outstanding, in each of the Trust's assets as determined in the case of Bitcoin by reference to the Index Price, less the Trust's expenses and other liabilities (which include accrued but unpaid fees and expenses). The Sponsor expects that the market price of the Shares will fluctuate over time in response to the market prices of Bitcoin. In addition, because the Shares reflect the estimated accrued but unpaid expenses of the Trust, the number of Bitcoin represented by a Share will gradually decrease over time as the Trust's Bitcoin is used to pay the Trust's expenses. The Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for purposes of determining the Trust's Digital Asset Holdings or the Digital Asset Holdings per Share.

The Sponsor will evaluate the Bitcoin held by the Trust and determine the Digital Asset Holdings of the Trust in accordance with the relevant provisions of the Trust Documents. The following is a description of the material terms of the Trust Documents as they relate to valuation of the Trust's Bitcoin and the Digital Asset Holdings calculations.

On each business day at 4:00 p.m., New York time, or as soon thereafter as practicable (the ''Evaluation Time''), the Sponsor will evaluate the Bitcoin held by the Trust and calculate and publish the Digital Asset Holdings of the Trust. To calculate the Digital Asset Holdings, the Sponsor will:

1. Determine the Index Price as of such business day.
2. Multiply the Index Price by the Trust's aggregate number of Bitcoins owned by the Trust as of 4:00 p.m., E.T. on the immediately preceding day, less the aggregate number of Bitcoins payable as the accrued and unpaid Sponsor's Fee as of 4:00 p.m., E.T. on the immediately preceding day.
3. Add the U.S. dollar value of Bitcoins, calculated using the Index Price, receivable under pending creation orders, if any, determined by multiplying the number of the Baskets represented by such creation orders by the Basket Amount and then multiplying such product by the Index Price.[15]
4. Subtract the U.S. dollar amount of accrued and unpaid Additional Trust Expenses, if any.
5. Subtract the U.S. dollar value of the Bitcoins, calculated using the Index Price, to be distributed under pending redemption orders, if any, determined by multiplying the number of Baskets to be redeemed represented by such redemption orders by the Basket Amount and then multiplying such product by the Index Price (the amount derived from steps 1 through 5 above, the ''Digital Asset Holdings Fee Basis Amount'').
6. Subtract the U.S. dollar amount of the Sponsor's Fee that accrues for such business day, as calculated based on the Digital Asset Holdings Fee Basis Amount for such business day.

In the event that the Sponsor determines that the primary methodology used to determine the Index Price is not an appropriate basis for valuation of the Trust's Bitcoins, the Sponsor will utilize the cascading set of rules as described in ''Trust Valuation of

[14] The Digital Asset Account is a segregated custody account controlled and secured by the Custodian to store private keys, which allows for the transfer of ownership or control of the Trust's Bitcoins on the Trust's behalf.

[15] ''Baskets'' and ''Basket Amount'' have the meanings set forth in ''Creation of Shares'' below.

Bitcoin'' below. In addition, in the event that the Trust holds any Incidental Rights and/or IR Virtual Currency, the Sponsor may, at its discretion, include the value of such Incidental Rights and/or IR Virtual Currency in the determination of the Digital Asset Holdings, provided that the Sponsor has determined in good faith a method for assigning an objective value to such Incidental Rights and/or IR Virtual Currency. At this time, the Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for the purposes of determining the Digital Asset Holdings or the Digital Asset Holdings per Share.

Limits on Bitcoin Supply

The supply of new Bitcoin is mathematically controlled so that the number of Bitcoin grows at a limited rate pursuant to a pre-set schedule. The number of Bitcoin awarded for solving a new block is automatically halved after every 210,000 blocks are added to the Blockchain. Currently, the fixed reward for solving a new block is 6.25 Bitcoin per block and this is expected to decrease by half to become 3.125 Bitcoin after the next 210,000 blocks have entered the Bitcoin Network, which is expected to be mid-2024. This deliberately controlled rate of Bitcoin creation means that the number of Bitcoin in existence will increase at a controlled rate until the number of Bitcoin in existence reaches the pre-determined 21 million Bitcoin. As of June 30, 2021, approximately 18.7 million Bitcoins were outstanding and the date when the 21 million Bitcoin limitation will be reached is estimated to be the year 2140.

Bitcoin Value

Digital Asset Exchange Valuation

According to the Annual Report, the value of Bitcoin is determined by the value that various market participants place on Bitcoin through their transactions. The most common means of determining the value of a Bitcoin is by surveying one or more Digital Asset Exchanges where Bitcoin is traded publicly (*e.g.,* Coinbase Pro, Bitstamp, Kraken, and LMAX Digital). Additionally, there are over-the-counter dealers or market makers that transact in Bitcoin.

Digital Asset Exchange Public Market Data

On each online Digital Asset Exchange, Bitcoin is traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. dollar or Euro. Over-the-counter dealers or market makers do not typically disclose their trade data.

As of June 30, 2021, the Digital Asset Exchanges included in the Index are Coinbase Pro, Bitstamp, Kraken and LMAX Digital. As further described below, each of these Digital Asset Exchanges are in compliance with applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations.

Coinbase Pro: A U.S.-based exchange registered as a money services business (''MSB'') with FinCen and licensed as a virtual currency business under the NYDFS BitLicense as well as money transmitter in various U.S. states.

Bitstamp: A U.K.-based exchange registered as an MSB with FinCen and licensed as a virtual currency business under the NYDFS BitLicense as well as money transmitter in various U.S. states.

Kraken: A U.S.-based exchange registered as an MSB with FinCen and licensed as money transmitter in various U.S. states. Kraken does not hold a BitLicense.

LMAX Digital: A U.K.-based exchange registered as a broker with FCA. LMAX Digital does not hold a BitLicense.

Currently, there are several Digital Asset Exchanges operating worldwide, and online Digital Asset Exchanges represent a substantial percentage of Bitcoin buying and selling activity and provide the most data with respect to prevailing valuations of Bitcoins. These exchanges include established exchanges such as exchanges included in the Index, which provide a number of options for buying and selling Bitcoins. The below table reflects the trading volume in Bitcoins and market share of the BTC–U.S. dollar trading pair of each of the Digital Asset Exchanges included in the Index as of June 30, 2021 using data reported by the Index Provider from May 1, 2015 to June 30, 2021:

Digital asset exchanges included in the index as of June 30, 2021 [16]	Volume (BTC)	Market share [17] (%)
Coinbase Pro	29,508,974	19.96
Bitstamp	21,579,385	14.60
Kraken	10,433,760	7.06
LMAX Digital	5,336,911	3.61
Total BTC–U.S. dollar trading pair	66,859,030	45.23

[16] On January 15, 2019, the Index Provider added Kraken back to the Index and also added Bittrex to the Index. On January 19, 2020, the Index Provider removed Bittrex and added LMAX Digital as part of its scheduled quarterly review. On April 6, 2020, the Index Provider removed itBit and did not add any constituents as part of its scheduled quarterly review.

[17] Market share is calculated using trading volume data (in Bitcoins) provided by the Index Provider for certain Digital Asset Exchanges, including Coinbase Pro, Bitstamp, Kraken, and LMAX Digital, as well as certain other large U.S.-dollar denominated Digital Asset Exchanges that are not currently included in the Index, including Binance. U.S. (data included from April 1, 2020), Bitfinex, Bitflyer (data included from December 24, 2018), Bittrex (data included from July 31, 2018), ErisX (data included from October 1, 2020), Gemini, itBit, LakeBTC (data included from May 1, 2015 to June 1, 2018 and from January 27, 2019), HitBTC (data included from April 1, 2019 to March 31, 2020) and OKCoin.

On January 19, 2020, as part of a scheduled quarterly review, the Index Provider delisted the Bittrex constituent and related BTC/USD currency pair and added the LMAX Digital constituent and related BTC/USD currency pair.

The domicile, regulation, and legal compliance of the Digital Asset Exchanges included in the Index varies. Information regarding each Digital Asset Exchange may be found, where available, on the websites for such Digital Asset Exchanges, among other places.

The Index and the Index Price

The Index is a U.S. dollar-denominated composite reference rate for the price of Bitcoin. The Index is designed to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of Bitcoin and (iii) appropriately handle and adjust for non-market related events.

The Index Price is determined by the Index Provider through a process in which trade data is cleansed and

compiled in such a manner as to algorithmically reduce the impact of anomalistic or manipulative trading. This is accomplished by adjusting the weight of each data input based on price deviation relative to the observable set, as well as recent and long-term trading volume at each venue relative to the observable set. To calculate volume weighted price, the weighting algorithm is applied to the price and volume of all inputs for the immediately preceding 24-hour period at 4:00 p.m., New York time, on the trade date.

Constituent Exchange Selection

According to the Annual Report, the Digital Asset Exchanges that are included in the Index are selected by the Index Provider utilizing a methodology that is guided by the International Organization of Securities Commissions (''IOSCO'') principles for financial benchmarks. For an exchange to become a Digital Asset Exchange included in the Index (a ''Constituent Exchange''), it must satisfy the criteria listed below (the ''Inclusion Criteria''):

- Compliance with applicable U.S. federal and state licensing requirements and practices regarding anti-money laundering (''AML'') and know-your-customer (''KYC'') regulations;
- Publicly known ownership;
- No restrictions on deposits and/or withdrawals of Bitcoin;
- No restrictions on deposits and/or withdrawals of U.S. dollars;
- Reliably displays new trade prices and volumes on a real-time basis through APIs;
- Programmatic trading [18] of the Bitcoin/U.S. dollar spot price;
- Liquid market in the Bitcoin/U.S. dollar spot price;
- Trading volume must represent a minimum of total Bitcoin/U.S. dollar trading volumes (5% for U.S. exchanges and 10% non-U.S. exchanges); and
- Discretion of the Index Provider's analysts [19]

A Digital Asset Exchange is removed from the Index when it no longer satisfies the Inclusion Criteria. The Index Provider does not currently include data from over-the-counter markets or derivatives platforms among the Constituent Exchanges. According to the Annual Report, over-the-counter data is not currently included because of the potential for trades to include a significant premium or discount paid for larger liquidity, which creates an uneven comparison relative to more active markets. There is also a higher potential for over-the-counter transactions to not be arms-length, and thus not be representative of a true market price. Bitcoin derivative markets are also not currently included as the markets remain relatively thin. The Index Provider will consider IOSCO principles for financial benchmarks and the management of trading venues of Bitcoin derivatives when considering inclusion of over-the-counter or derivative platform data in the future.

The Index Provider and the Sponsor have entered into an index license agreement (the ''Index License Agreement'') governing the Sponsor's use of the Index Price. The Index Provider may adjust the calculation methodology for the Index Price without notice to, or consent of, the Trust or its shareholders. The Index Provider may decide to change the calculation methodology to maintain the integrity of the Index Price calculation should it identify or become aware of previously unknown variables or issues with the existing methodology that it believes could materially impact its performance and/or reliability. The Index Provider has sole discretion over the determination of Index Price and may change the methodologies for determining the Index Price from time to time. Shareholders will be notified of any material changes to the calculation methodology or the Index Price in the Trust's current reports and will be notified of all other changes that the Sponsor considers significant in the Trust's periodic reports. The Trust will determine the materiality of any changes to the Index Price on a case-by-case basis, in consultation with external counsel.

The Index Provider may change the trading venues that are used to calculate the Index or otherwise change the way in which the Index is calculated at any time. For example, the Index Provider has scheduled quarterly reviews in which it may add or remove Constituent Exchanges that satisfy or fail the Inclusion Criteria. The Index Provider does not have any obligation to consider the interests of the Sponsor, the Trust, the shareholders, or anyone else in connection with such changes. The Index Provider is not required to publicize or explain the changes or to alert the Sponsor to such changes. Although the Index methodology is designed to operate without any manual intervention, rare events would justify manual intervention. Intervention of this kind would be in response to non-market-related events, such as the halting of deposits or withdrawals of funds on a Digital Asset Exchange, the unannounced closure of operations on a Digital Asset Exchange, insolvency or the compromise of user funds. In the event that such an intervention is necessary, the Index Provider would issue a public announcement through its website, API and other established communication channels with its clients.

Determination of the Index Price

The Index applies an algorithm to the 24-hour volume-weighted average price of Bitcoin on the Constituent Exchanges calculated on a per second basis. The Index's algorithm is expected to reflect a four-pronged methodology to calculate the Index Price from the Constituent Exchanges:

- *Volume Weighting:* Constituent Exchanges with greater liquidity receive a higher weighting in the Index Price, increasing the ability to execute against (*i.e.,* replicate) the Index in the underlying spot markets.
- *Price-Variance Weighting:* The Index Price reflects data points that are discretely weighted in proportion to their variance from the rest of the other Constituent Exchanges. As the price at a particular exchange diverges from the prices at the rest of the Constituent Exchanges, its weight in the Index Price consequently decreases.
- *Inactivity Adjustment:* The Index Price algorithm penalizes stale activity from any given Constituent Exchange. When a Constituent Exchange does not have recent trading data, its weighting in the Index Price is gradually reduced until it is de-weighted entirely. Similarly, once trading activity at a Constituent Exchange resumes, the corresponding weighting for that Constituent Exchange is gradually increased until it reaches the appropriate level.
- *Manipulation Resistance:* In order to mitigate the effects of wash trading and order book spoofing, the Index Price only includes executed trades in its calculation. Additionally, the Index Price only includes Constituent Exchanges that charge trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts.

The Index Provider formally re-evaluates the weighting algorithm quarterly, but maintains discretion to change the way in which an Index Price is calculated based on its periodic review or in extreme circumstances. The Index is designed to limit exposure to trading or price distortion of any individual Digital Asset Exchange that experiences periods of unusual activity or limited liquidity by discounting, in

[18] Exchanges with programmatic trading offer traders an application programming interface that permits trading by sending programmed commands to the exchange.

[19] This includes additional due diligence conducted by the Index Provider's analysts.

real-time, anomalous price movements at individual Digital Asset Exchanges.

The Sponsor believes the Index Provider's selection process for Constituent Exchanges as well as the methodology of the Index Price's algorithm provides a more accurate picture of Bitcoin price movements than a simple average of Digital Asset Exchange spot prices, and that the weighting of Bitcoin prices on the Constituent Exchanges limits the inclusion of data that is influenced by temporary price dislocations that may result from technical problems, limited liquidity or fraudulent activity elsewhere in the Bitcoin spot market. By referencing multiple trading venues and weighting them based on trade activity, the Sponsor believes that the impact of any potential fraud, manipulation or anomalous trading activity occurring on any single venue is reduced.

If the Index Price becomes unavailable, or if the Sponsor determines in good faith that such Index Price does not reflect an accurate price for Bitcoin, then the Sponsor will, on a best efforts basis, contact the Index Provider to obtain the Index Price directly from the Index Provider. If after such contact such Index Price remains unavailable or the Sponsor continues to believe in good faith that such Index Price does not reflect an accurate price for the relevant digital asset, then the Sponsor will employ a cascading set of rules to determine the Index Price, as described below in ''—Determination of the Index Price When Index Prices are Unavailable.''

The Trust values its Bitcoin for operational purposes by reference to the Index Price. The Index Price is the value of a Bitcoin as represented by the Index, calculated at 4:00 p.m., New York time, on each business day. The Index Provider develops, calculates and publishes the Index on a continuous basis using the volume-weighted price at the Digital Asset Benchmark Exchanges, as selected by the Index Provider.

Illustrative Example

For the purposes of illustration, outlined below are examples of how the attributes that impact weighting and adjustments in the aforementioned methodology may be utilized to generate the Index Price for a digital asset. For example, the Constituent Exchanges for the Index Price of the digital asset are Coinbase Pro, Kraken, LMAX Digital and Bitstamp.

The Index Price algorithm, as described above, accounts for manipulation at the outset by only including data from executed trades on Constituent Exchanges that charge trading fees. Then, the below-listed elements may impact the weighting of the Constituent Exchanges on the Index price as follows:

- *Volume Weighting:* Each Constituent Exchange will be weighted to appropriately reflect the trading volume share of the Constituent Exchange relative to all the Constituent Exchanges during this same period. For example, an average hourly weighting of 52.17%, 11.88%, 24.46% and 11.49% for Coinbase Pro, Kraken, LMAX Digital and Bitstamp, respectively, would represent each Constituent Exchange's share of trading volume during the same period.
- *Inactivity Adjustment:* Assume that a Constituent Exchange's trading engine represented a 14% influence on the trading price of the digital asset and then went offline for approximately two hours. The index algorithm automatically recognizes inactivity and de-weights that Constituent Exchange's influence in the Index Price—for example, from 14% to 0%—until trading activity resumes. At which point it would re-weight the Constituent Exchange activity to a weight lower than its original weighting—for example, to 12%.
- *Price-Variance Weighting:* Assume that for a one-hour period, the digital asset's execution prices on one Constituent Exchange were trading more than 7% higher than the average execution prices on another Constituent Exchange. The algorithm will automatically detect the anomaly and reduce that specific Constituent Exchange's weighting to 0% for that one-hour period, ensuring a reliable spot reference unaffected by the localized event.

Determination of the Index Price When Index Price Is Unavailable

In case of the unavailability of the Index Price, the Sponsor will use the following cascading set of rules to calculate the Index Price. For the avoidance of doubt, the Sponsor will employ the below rules sequentially and in the order as presented below, should one or more specific rule(s) fail:

1. Index Price = The price set by the Index as of 4:00 p.m., E.T., on the valuation date. If the Index becomes unavailable, or if the Sponsor determines in good faith that the Index does not reflect an accurate Bitcoin price, then the Sponsor will, on a best efforts basis, contact the Index Provider to obtain the Index Price directly from the Index Provider. If after such contact the Index remains unavailable or the Sponsor continues to believe in good faith that the Index does not reflect an accurate Bitcoin price, then the Sponsor will employ the next rule to determine the Index Price.

2. Index Price = The volume-weighted average Bitcoin price for the immediately preceding 24-hour period at 4:00 p.m., E.T., on the trade date as published by a third party's public data feed that is reasonably reliable, subject to the requirement that such data is calculated based upon a volume-weighted price obtained from the major Digital Asset Exchanges (the ''Source''). Subject to the next sentence, if the Source becomes unavailable (*e.g.,* data sources from the Source for Bitcoin prices become unavailable, unwieldy or otherwise impractical for use) or if the Sponsor determines in good faith that the Source does not reflect an accurate Bitcoin price, then the Sponsor will, on a best efforts basis, contact the Source in an attempt to obtain the relevant data. If after such contact the Source remains unavailable after such contact or the Sponsor continues to believe in good faith that the Source does not reflect an accurate Bitcoin price, then the Sponsor will employ the next rule to determine the Index Price.

3. Index Price = The volume-weighted average price as calculated by dividing the sum of the total volume of Bitcoin transactions in U.S. dollar by the total volume of transactions in Bitcoin, in each case for the immediately preceding 24-hour period as of 4:00 p.m., E.T., on the trade date as published by a third party's public data feed that is reasonably reliable, subject to the requirement that such data is calculated based upon a volume-weighted price obtained from the major Digital Asset Exchanges (the ''Second Source''). Subject to the next sentence, if the Second Source becomes unavailable (*e.g.,* data sources from the Second Source become unavailable, unwieldy or otherwise impractical for use) or if the Sponsor determines in good faith that the Second Source does not reflect an accurate Bitcoin price, then the Sponsor will, on a best efforts basis, contact the Second Source in an attempt to obtain the relevant data. If after such contact the Second Source remains unavailable after such contact or the Sponsor continues to believe in good faith that the Second Source does not reflect an accurate Bitcoin price, then the Sponsor will employ the next rule to determine the Index Price.

4. Index Price = The volume-weighted average price as calculated by dividing the sum of the total volume of Bitcoin transactions in U.S. dollar by the total volume of transactions in Bitcoin, in each case for the immediately preceding 24-hour period as of 4:00 p.m., E.T., on the trade date on the Digital Asset benchmark exchanges that represent at least 25% of the aggregate trading volume of the Digital Asset Exchange Market during the last 30 consecutive calendar days and that to the knowledge of the Sponsor are in substantial compliance with the laws, rules and regulations, including any anti-money laundering and know-your-customer procedures (collectively, ''Digital Asset Benchmark Exchanges''). If there are fewer than three individual Digital Asset Benchmark Exchanges each of which represent at least 25% of the aggregate trading volume on the

Digital Asset Exchange Market during the last 30 consecutive calendar days, then the Digital Asset Benchmark Exchanges that will serve as the basis for the Index Price calculation will be those Digital Asset Benchmark Exchanges that meet the above-described requirements, as well as one or more additional Digital Asset Exchanges, as selected by the Sponsor, that has had a monthly trading volume of at least 50,000 Bitcoin during the last 30 consecutive calendar days.

The Sponsor will review the composition of the exchanges that comprise the Digital Asset Benchmark Exchanges at the beginning of each month in order to ensure the accuracy of such composition.

Subject to the next sentence, if one or more of the Digital Asset Benchmark Exchanges become unavailable (*e.g.,* data sources from the Digital Asset Benchmark Exchanges of Bitcoin prices becomes unavailable, unwieldy or otherwise impractical for use) or if the Sponsor determines in good faith that one or more Digital Asset Benchmark Exchanges do not reflect an accurate Bitcoin price, then the Sponsor will, on a best efforts basis, contact the Digital Asset Benchmark Exchange that is experiencing the service outages in an attempt to obtain the relevant data. If after such contact one or more of the Digital Asset Benchmark Exchanges remain unavailable after such contact or the Sponsor continues to believe in good faith that one or more Digital Asset Benchmark Exchanges do not reflect an accurate Bitcoin price, then the Sponsor will employ the next rule to determine the Index Price

5. Index Price = The Sponsor will use its best judgment to determine a good faith estimate of the Index Price.

In the event of a fork, the Index Provider may calculate the Index Price based on a virtual currency that the Sponsor does not believe to be the appropriate asset that is held by the Trust.[20] In this event, the Sponsor has full discretion to use a different index provider or calculate the Index Price itself using its best judgment.

The Structure and Operation of the Trust Protects Investors and Satisfies Commission Requirements for Bitcoin-Based Exchange Traded Products

The Commission has expressed legitimate concerns about the underlying Digital Asset Market due to the potential for fraud and manipulation and has clearly outlined the reasons why prior Bitcoin-based ETP proposals have been unable to satisfy these concerns in orders disapproving the proposed listing and trading of the Winklevoss Bitcoin Trust, Bitwise Bitcoin ETF Trust, United States Bitcoin and Treasury Investment Trust, and various Bitcoin-based trust issued receipts.[21]

In these disapproval orders, the Commission outlined that a proposal relating to a Bitcoin-based ETP could satisfy its concerns regarding potential for fraud and manipulation by demonstrating:

(1) *Inherent Resistance to Fraud and Manipulation:* that the underlying commodity market is inherently resistant to fraud and manipulation;

(2) *Other Means to Prevent Fraud and Manipulation:* that there are other means to prevent fraudulent and manipulative acts and practices that are sufficient; or

(3) *Surveillance Sharing:* that the listing exchange has entered into a surveillance sharing agreement with a regulated market of significant size relating to the underlying or reference assets.

As described below, the Sponsor believes the structure and operation of the Trust are designed to prevent fraudulent and manipulative acts and practices, to protect investors and the public interest, and to respond to the specific concerns that the Commission has identified with respect to potential fraud and manipulation in the context of a Bitcoin-based ETP.

How the Trust Meets Standards in the Winklevoss Order, Bitwise Order and Wilshire Phoenix Order

1. Resistance to or Prevention of Fraud and Manipulation

In the Bitwise Order, the Commission disagreed with the proposition that Bitcoin's fungibility, transportability and exchange tradability combine to provide unique protections against, and allow Bitcoin to be uniquely resistant to, attempts at price manipulation. The Commission reached its conclusion based on concessions by Bitwise that 95% of the reported trading in Bitcoin is ''fake'' or non-economic, effectively admitting that the properties of Bitcoin do not make it inherently resistant to manipulation. Bitwise's concessions were further compounded by evidence of potential and actual fraud and manipulation in the historical trading of Bitcoin on certain marketplaces such as (1) ''wash'' trading, (2) trading based on material, non-public information, including the dissemination of false and misleading information, (3) manipulative activity involving Tether, and (4) fraud and manipulation.[22]

[20] According to the Annual Report, when a modification is introduced and a substantial majority of users and miners consent to the modification, the change is implemented and the network remains uninterrupted. However, if less than a substantial majority of users and miners consent to the proposed modification, and the modification is not compatible with the software prior to its modification, the consequence would be what is known as a ''hard fork'' of the Bitcoin Network, with one group running the pre-modified software and the other running the modified software. The effect of such a fork would be the existence of two versions of Bitcoin running in parallel, yet lacking interchangeability. For example, in August 2017, Bitcoin ''forked'' into Bitcoin and a new digital asset, Bitcoin Cash, as a result of a several-year dispute over how to increase the rate of transactions that the Bitcoin Network can process. In the event of a hard fork of the Bitcoin Network, the Sponsor will, if permitted by the terms of the Trust Agreement, use its discretion to determine, in good faith, which peer-to-peer network, among a group of incompatible forks of the Bitcoin Network, is generally accepted as the Bitcoin Network and should therefore be considered the appropriate network for the Trust's purposes. The Sponsor will base its determination on a variety of then relevant factors, including, but not limited to, the Sponsor's beliefs regarding expectations of the core developers of Bitcoin, users, services, businesses, miners, and other constituencies, as well as the actual continued acceptance of, mining power on, and community engagement with, the Bitcoin Network. There is no guarantee that the Sponsor will choose the digital asset that is ultimately the most valuable fork, and the Sponsor's decision may adversely affect the value of the Shares as a result. The Sponsor may also disagree with shareholders, security vendors, and the Index Provider on what is generally accepted as Bitcoin and should therefore be considered ''Bitcoin'' for the Trust's purposes, which may also adversely affect the value of the Shares as a result.

[21] *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (the ''Winklevoss Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the Bitwise Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 87267 (Oct. 9, 2019), 84 FR 55382 (Oct. 16, 2019) (SR–NYSEArca–2019–01) (the ''Bitwise Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and to List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (the ''Wilshire Phoenix Order''); Order Disapproving a Proposed Rule Change to List and Trade the Shares of the ProShares Bitcoin ETF and the ProShares Short Bitcoin ETF, Securities Exchange Act Release No. 83904 (Aug. 22, 2018), 83 FR 43934 (Aug. 28, 2018) (SR–NYSEArca–2017–139) (the ''ProShares Order''); Order Disapproving a Proposed Rule Change Relating to Listing and Trading of the Direxion Daily Bitcoin Bear 1X Shares, Direxion Daily Bitcoin 1.25X Bull Shares, Direxion Daily Bitcoin 1.5X Bull Shares, Direxion Daily Bitcoin 2X Bull Shares, and Direxion Daily Bitcoin 2X Bear Shares Under NYSE Arca Rule 8.200–E, Securities Exchange Act Release No. 83912 (Aug. 22, 2018), 83 FR 43912 (Aug. 28, 2018) (SR–NYSEArca–2018–02) (the ''Direxion Order''); Order Disapproving a Proposed Rule Change to List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF, Securities Exchange Act Release No. 83913 (Aug. 22, 2018), 83 FR 43923 (Aug. 28, 2018) (SR–CboeBZX–2018–01) (the ''GraniteShares Order'').

[22] *See* Bitwise Order, 84 FR 55383 (discussing analysis of the Bitcoin spot market that asserts that 95% of the spot market is dominated by fake and non-economic activity, such as wash trades), 55391 (discussing possible sources of fraud and manipulation in the bitcoin spot market). *See also* Winklevoss Order, 83 FR 37585–86 (discussing pending litigation against a Bitcoin trading platform

Continued

The Sponsor acknowledges the possibility that fraud and manipulation may exist and that Bitcoin trading *on any given exchange* may be no more uniquely resistant to fraud and manipulation than other commodity markets.[23] However, the Sponsor believes that the fundamental features of Bitcoin's fungibility, transportability and exchange tradability offer novel protections beyond those that exist in traditional commodity markets or equity markets when combined with other means, as discussed further below.

2. Other Means To Prevent Fraud and Manipulation

The Commission has recognized that a listing exchange could demonstrate that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[24] In evaluating the effectiveness of this type of resistance, the Commission does not apply a ''cannot be manipulated'' standard. Instead, the Commission requires that such resistance to fraud and manipulation be novel and beyond those protections that exist in traditional commodity markets or equity markets for which the Commission has long required surveillance-sharing agreements in the context of listing derivative securities products.[25]

The Sponsor believes the Index represents a novel means to prevent fraud and manipulation from impacting a reference price for Bitcoin and that it offers protections beyond those that exist in traditional commodity markets or equity markets. Specifically, Bitcoin is novel and exists outside traditional commodity markets. It therefore stands to reason that the methods in which it trades will be novel and that the market for Bitcoin will have different attributes than traditional commodity markets. Bitcoin was only introduced within the past decade, twenty years after the first U.S. ETFs were offered[26] and 150 years after the first futures were offered.[27] In contrast to older commodities such as gold, silver, platinum, palladium or copper, which the Commission has noted all had at least one significant, regulated market for trading futures on the underlying commodity at the time commodity trust ETPs were approved for listing and trading, the first trading in Bitcoin took place entirely in an open, transparent and online setting where other commodities cannot trade.

The Trust has priced its Shares consistently for more than six years based on the Index. The Sponsor believes the Trust's use of the Index specifically addresses the Commission's concerns in that the Index serves as an alternative means to prevent fraud and manipulation. Specifically, the Index can (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of Bitcoin and (iii) appropriately handle and adjust for non-market related events.

As described in more detail below, the Sponsor believes that the Index accomplishes those objectives in the following ways:

1. The Index tracks the Digital Asset Exchange Market Price through trading activity at ''U.S.-Compliant Exchanges''; [28]
2. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments;
3. The Index is constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events;
4. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific exchange through a cross-exchange composite index rate; and
5. The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity occurring on multiple exchanges by using a 24-hour window to weight the activity at each exchange through a 24-hour Volume Weighted Average Price (''VWAP'').

1. *The Index tracks the Digital Asset Exchange Market Price through trading activity at ''U.S.-Compliant Exchanges''.*

To reduce the risk of fraud, manipulation, and other anomalous trading activity from impacting the Index, only U.S.-Compliant Exchanges are eligible to be included in the Index.

The Index maintains a minimum number of three exchanges and a maximum number of five exchanges to track the Digital Asset Exchange Market while offering replicability for traders and market makers.[29]

U.S.-Compliant Exchanges possess safeguards that protect against fraud and manipulation. For example, U.S.-Compliant Exchanges regulated by the New York State Department of Financial Services (''NYDFS'') under the BitLicense program have regulatory requirements to implement measures designed to effectively detect, prevent, and respond to fraud, attempted fraud, market manipulation, and similar wrongdoing, and to monitor, control, investigate and report back to the NYDFS regarding any wrongdoing.[30] These exchanges also have the following obligations: [31]

- Submission of audited financial statements including income statements, statement of assets/liabilities, insurance, and banking;
- Compliance with capitalization requirements set at NYDFS's discretion;
- Prohibitions against the sale or encumbrance to protect full reserves of custodian assets;
- Fingerprints and photographs of employees with access to customer funds;
- Retention of a qualified Chief Information Security Officer and annual penetration testing/audits;
- Documented business continuity and disaster recovery plan, independently tested annually; and

for fraudulent conduct relating to Tether); Bitwise Order, 84 FR 55391 n.140, 55402 & n.331 (same); Winklevoss Order, 83 FR 37584–86 (discussing potential types of manipulation in the Bitcoin spot market). The Commission has also noted that fraud and manipulation in the Bitcoin spot market could persist for a significant duration. *See, e.g.,* Bitwise Order, 84 FR 55405 & n.379.

[23] *See generally* Bitwise Order.

[24] *See* Winklevoss Order, 84 FR 37580, 37582–91; Bitwise Order, 84 FR 55383, 55385–406; Wilshire Phoenix Order, 85 FR 12597.

[25] *See* Winklevoss Order, 84 FR 37582; Wilshire Phoenix Order, 85 FR 12597.

[26] SEC, ''Investor Bulletin: Exchange-Traded Funds (ETFs),'' August 2012, *https://www.sec.gov/investor/alerts/etfs.pdf.*

[27] CFTC, ''History of the CFTC,'' *https://www.cftc.gov/About/HistoryoftheCFTC/history_precftc.html.*

[28] ''U.S.-Compliant Exchanges'' are exchanges in the Digital Asset Exchange Market that are compliant with applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations. All Constituent Exchanges are U.S.-Compliant Exchanges.

''Non-U.S.-Compliant Exchanges'' are all other exchanges in the Digital Asset Exchange Market.

As of June 30, 2021, the U.S.-Compliant Exchanges that the Index Provider considered for inclusion in the Index were Bitstamp, Coinbase Pro, Kraken and LMAX Digital.

From these U.S.-Compliant Exchanges, the Index Provider then applies additional Inclusion Criteria to determine the Constituent Exchange. As of June 30, 2021, the Constituent Exchanges were Bitstamp, Coinbase Pro, Kraken, and LMAX Digital.

[29] According to the Sponsor, the more exchanges included in the Index, the more ability there is for traders and market makers to trade against the Index by arbitraging price differences. For example, in the event of variances between Bitcoin prices on Constituent Exchanges and non-Constituent Exchanges, arbitrage trading opportunities would exist. These discrepancies generally consolidate over time, as price differences across exchanges are realized and capitalized upon by traders and market makers.

[30] *See, e.g.,* ''DFS Takes Action to Deter Fraud and Manipulation in Virtual Currency Markets,'' available at *https://www.dfs.ny.gov/about/press/pr1802071.htm.*

[31] *See* ''New York's Final ''BitLicense'' Rule: Overview and Changes from July 2014 Proposal,'' June 5, 2015, Davis Polk, available at *https://www.davispolk.com/files/new_yorks_final_bitlicense_rule_overview_changes_july_2014_proposal.pdf.*

• Participation in an independent exam by NYDFS.

Other U.S.-Compliant Exchanges have voluntarily implemented measures to protect against common forms of market manipulation.[32]

Furthermore, all U.S.-Compliant Exchanges are considered Money Services Businesses (''MSBs'') that are subject to federal and state reporting requirements of the U.S Department of Treasury's FinCEN division that provide additional safeguards. For example, unscrupulous traders may be less likely to engage in fraudulent or manipulative acts and practices on exchanges that (1) report suspicious activity to FinCEN as money services businesses, (2) report to state regulators as money transmitters, and/or (3) require customer identification through KYC procedures. U.S.-Compliant Exchanges are required to:[33]

• Identify people with ownership stakes or controlling roles in the MSB;

• Establish a formal Anti-Money Laundering (AML) policy in place with documentation, training, independent review, and a named compliance officer;

• Implement strict customer identification and verification policies and procedures;

• File Suspicious Activity Reports (SARs) for suspicious customer transactions;

• File Currency Transaction Reports (CTRs) for cash-in or cash-out transactions greater than $10,000; and

• Maintain a five-year record of currency exchanges greater than $1,000 and money transfers greater than $3,000.

Lastly, because of Bitcoin's classification as a commodity, the CFTC has authority to police fraud and manipulation on U.S.-Compliant Exchanges.

The Sponsor acknowledges that there are substantial differences between FinCEN and New York state regulations and the Commission's regulation of the national securities exchanges.[34] The Sponsor does not believe the inclusion of U.S.-Compliant Exchanges is in and of itself sufficient to prove that the Index is an alternative means to prevent fraud and manipulation such that surveillance sharing agreements are not required, but does believe that the inclusion of only U.S.-Compliant Exchanges in the Index is one significant way in which the Index is protected from the potential impacts of fraud and manipulation.

2. *The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments.*

The Index is calculated once every second according to a systematic methodology that relies on observed trading activity on the Constituent Exchanges. While the precise methodology underlying the Index is currently proprietary, the key elements of the Index are outlined below:

• *Volume Weighting:* Constituent Exchanges with greater liquidity receive a higher weighting in the Index, increasing the ability to execute against (*i.e.,* replicate) the Index in the underlying spot markets.

• *Price-Variance Weighting:* The Index reflects data points that are discretely weighted in proportion to their variance from the rest of the Constituent Exchanges. As the price at a Constituent Exchange diverges from the prices at the rest of the Constituent Exchanges, its weight in the Index consequently decreases.

• *Inactivity Adjustment:* The Index algorithm penalizes stale activity from any given Constituent Exchange. When a Constituent Exchange does not have recent trading data, its weighting in the Index is gradually reduced, until it is de-weighted entirely. Similarly, once trading activity at the Constituent Exchange resumes, the corresponding weighting for that Constituent Exchange is gradually increased until it reaches the appropriate level.

• *Manipulation Resistance:* In order to mitigate the effects of wash trading and order book spoofing, the Index only includes executed trades in its calculation. Additionally, the Index only includes Constituent Exchanges that charge trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts.

The Index Provider reviews and periodically updates the exchanges included in the Index by utilizing a methodology that is guided by the IOSCO principles for financial benchmarks.

3. *The Index is constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events.*

The Index Provider reviews and periodically updates which exchanges are included in the Index by utilizing a methodology that is guided by the IOSCO principles for financial benchmarks.

For an exchange to become a Constituent Exchange, it must satisfy the following Inclusion Criteria:

• Compliance with any applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations (*i.e.,* the Constituent Exchange must be a U.S.-Compliant Exchange);

• Publicly known ownership entity;

• No restrictions on deposits and/or withdrawals of Bitcoin;

• No restrictions on deposits and/or withdrawals of USD;

• Reliably publish trade prices and volumes on a real-time basis through APIs;

• Charges trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts;

• Offer programmatic trading of the Bitcoin/USD spot price;

• Liquid market in the Bitcoin/USD pair;

• Trading volume that represents a minimum of total Bitcoin/USD trading volumes (5% for U.S. exchanges and 10% non-U.S. exchanges); and

• Discretion of the Index Provider's analysts.

Although the Index methodology is designed to operate without any human interference, rare events would justify manual intervention. Manual intervention would only be in response to ''non-market-related events'' (*e.g.,* halting of deposits or withdrawals of funds, unannounced closure of exchange operations, insolvency, compromise of user funds, etc.). In the event that such an intervention is necessary, the Index Provider would issue a public announcement through its website, API and other established communication channels with its clients.[35]

4. *The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific exchange through a cross-exchange composite index rate.*

The Index is based on the price and volume data of multiple U.S.-Compliant Exchanges that satisfy the Index Provider's Inclusion Criteria. By referencing multiple trading venues and weighting them based on trade activity, the impact of any potential fraud, manipulation, or anomalous trading activity occurring on any single venue is reduced. Specifically, the effects of fraud, manipulation, or anomalous trading activity occurring on any single venue are de-weighted and consequently diluted by non-anomalous trading activity from other Constituent Exchanges.

[32] As of the date of filing, two of the four Constituent Exchanges, Bitstamp and Coinbase Pro, are regulated by NYDFS.

[33] *See* BSA Requirements for MSBs, FinCEN website: *https://www.fincen.gov/bsarequirements-msbs.*

[34] *See* Bitwise Order, 84 FR 55392; Wilshire Phoenix Order, 85 FR 12603.

[35] To the extent any such intervention has a material impact on the Trust, the Sponsor will also issue a public announcement.

Although the Index is designed to accurately capture the market price of Bitcoin, third parties may be able to purchase and sell Bitcoin on public or private markets included or not included among the Constituent Exchanges, and such transactions may take place at prices materially higher or lower than the Index Price. For example, based on data provided by the Index Provider, on any given day during the six months ended June 30, 2021, the maximum differential between the 4:00 p.m., New York time spot price of any single Digital Asset Exchange included in the Index and the Index Price was 8.50% and the average of the maximum differentials of the 4:00 p.m., New York time spot price of each Digital Asset Exchange included in the Index and the Index Price was 8.47%. During this same period, the average differential between the 4:00 p.m., New York time spot prices of all the Digital Asset Exchanges included in the Index and the Index Price was 0.27%.[36]

5. *The Index mitigates the impact of instances of fraud, manipulation and other anomalous trading activity occurring on multiple exchanges by using a 24-hour window to weight the activity at each exchange through a 24-hour VWAP.*

In addition to the methodological enhancements offered by the Index, the Index Price represents a weighted average of the mean Bitcoin/USD price of all its Constituent Exchanges, calculated on a second per second basis, using observed trading activity on the Constituent Exchanges over the preceding 24-hour period.

The Sponsor believes that applying a 24-hour VWAP to the Index ensures that any fraudulent, manipulative or anomalous trading activity across the multiple Constituent Exchanges would have a negligible impact on the Index Price unless sustained for an extended period of time, and such a manipulation attempt would be prohibitively expensive to sustain over 24-hour period.

The effectiveness of a 24-hour VWAP as a ''smoothing'' mechanism to mitigate the impact of instances of fraud, manipulation or anomalous trading activity on the price of an asset can be measured as ''Volatility Reduction'' or ''Improvement.'' The Sponsor represents that the Index Price experienced 12.1% lower annualized volatility (*i.e.,* a 16.5% improvement) as compared to the Global Digital Asset Market Price.

Since November 1, 2014, the Trust has consistently priced its Shares at 4:00 p.m., E.T. based on the Index Price. While that pricing would be known to the market, the Sponsor believes that, even if efforts to manipulate the price of Bitcoin at 4:00 p.m., E.T. were successful on any exchange, such activity would have had a negligible effect on the pricing of the Trust, due to the controls embedded in the structure of the Index.

Accordingly, the Sponsor believes that the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of Bitcoin and (iii) appropriately handle and adjust for non-market related events. For these reasons, the Sponsor believes that the Index represents an effective alternative means to prevent fraud and manipulation and the Trust's reliance on the Index addresses the Commission's concerns with respect to potential fraud and manipulation.

3. A Significant, Regulated and Surveilled Market Exists and Is Closely Connected With Spot Market for Bitcoin

In the Winklevoss Order, Bitwise Order and Wilshire Phoenix Order, the Commission described both the need for and the definition of a surveilled market of significant size for commodity-trust ETPs like the Trust to date.[37] Specifically, the Commission explained that:

> for the commodity-trust ETPs approved to date for listing and trading, there has been in every case at least one significant, regulated market for trading futures on the underlying commodity—whether gold, silver, platinum, palladium, or copper—and the ETP listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group membership in common with, that market.[38]

Further, the Commission stated that its interpretation of the term ''market of significant size'' depends on the interrelationship between the market with which the listing exchange has a surveillance-sharing agreement and the proposed ETP.[39] Accordingly, the terms ''significant market'' and ''market of significant size'' could mean:

> a market (or group of markets) as to which (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[40]

In the context of Bitcoin-based ETPs specifically, the Commission has stated that establishing a lead-lag relationship between the Bitcoin futures market and the spot market is central to understanding whether it is reasonably likely that a would-be manipulator of the ETP would need to trade on the Bitcoin futures market to successfully manipulate prices on those spot platforms that feed into the proposed ETP's pricing mechanism such that a surveillance-sharing agreement would assist the ETP listing market in detecting and deterring misconduct.[41] In particular, if the spot market leads the futures market, this would indicate that it would not be necessary to trade on the futures market to manipulate the proposed ETP, even if arbitrage worked efficiently, because the futures price would move to meet the spot price.

The Sponsor has conducted a lead/lag analysis of per minute data comparing the Bitcoin futures market, as represented by the CME futures market, to the Bitcoin spot market, as represented by the Index. Based on this analysis, the Sponsor has concluded that there does not appear to be a significant lead/lag relationship between the two instruments for the period of November 1, 2019 to August 31, 2021.

Although there is no significant lead/lag relationship, the Sponsor believes that the CME futures market represents a large, surveilled and regulated market. For example, from November 1, 2019 to August 31, 2021, the CME futures market trading volume was over $432 billion, compared to $624 billion in trading volume across the Constituent Exchanges included in the Index. With over 69% of the Index trading volume, the CME futures market represents significant coverage of U.S.-Compliant Exchanges in the Bitcoin market. In addition, the CME futures market

[36] The timeframe chosen reflects the longest continuous period during which the Digital Asset Exchanges that are currently included in the Index have been constituents. All Digital Asset Exchanges that were included in the Index throughout the period were considered in this analysis.

[37] *See* Winklevoss Order, 83 FR 37593–94; Bitwise Order, 84 FR 55383, 55410; Wilshire Phoenix Order, 85 FR 12609.

[38] *See* Winklevoss Order, 83 FR 37594.

[39] *See* Winklevoss Order, 83 FR 37594; Bitwise Order, 84 FR 55410; ProShares Order, 83 FR 43936; GraniteShares Order, 83 FR 43925; Direxion Order, 83 FR 43914; Wilshire Phoenix Order, 85 FR 12609.

[40] *See* Winklevoss Order, 83 FR 37594. This definition is illustrative and not exclusive. There could be other types of ''significant markets'' and ''markets of significant size,'' but this definition is an example that will provide guidance to market participants.

[41] *See* Bitwise Order, 84 FR 55411; Wilshire Phoenix Order, 85 FR 12612.

trading volume from November 1, 2019 to August 31, 2021 was approximately 50% of the trading volume of the U.S. dollar-denominated Bitcoin spot markets referenced in the Bitwise Order.[42]

Given the significant size of the CME futures markets, the Sponsor believes there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, since arbitrage between the derivative and spot markets would tend to counter an attempt to manipulate the spot market alone. As a result, the Exchange's ability to obtain information regarding trading in the Shares and futures from markets and other entities that are members of the Intermarket Trading Group (''ISG''), including the CME, would assist the Exchange in detecting and deterring misconduct.

The Sponsor also believes it is unlikely that the ETP would become the predominant influence on prices in the market.

While future inflows to the proposed Trust cannot be predicted, to provide comparable data, the Sponsor examined the change in market capitalization of Bitcoin with net inflows into the Trust, which currently trades on OTC Markets and is largest and most liquid Bitcoin investment product in the world.[43] From November 1, 2019 to August 31, 2021, the market capitalization of Bitcoin grew from $166 billion to $888 billion, a $721 billion increase. Over the same period, the Trust experienced $6.6 billion of inflows. The cumulative inflow into the Trust over the stated time period was only 0.9% of the aggregate growth of Bitcoin's market capitalization.

Additionally, the Trust experienced approximately $98.5 billion of trading volume from November 1, 2019 to August 31, 2021, only 23% of the CME futures market and 16% of the Index over the same period.

* * * * *

In summary, the Sponsor believes that the foregoing responds to the Commission's articulated concerns with respect to potential fraud and manipulation in Bitcoin-based ETPs. Specifically, the Sponsor believes that, although Bitcoin is not itself inherently resistant to fraud and manipulation, the Index represents an effective means to prevent fraudulent and manipulative acts and practices. As discussed above, the Trust has used the Index to price the Shares for more than six years, and the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of bitcoin and (iii) appropriately handle and adjusts for non-market related events. The Sponsor also believes that the CME futures market is a significant, surveilled and regulated market that is closely connected with the spot market for Bitcoin and may fulfill the requirements for surveillance sharing given the Exchange's ability to obtain information from markets and other entities that are members of the ISG to assist in detecting and deterring misconduct.

The Chair's Remarks Regarding Bitcoin-Based ETP Proposals Registered Under the Investment Company Act of 1940

In an August 3, 2021 speech at the Aspen Security Forum, the Chair stated that he looked forward to the Commission's review of Bitcoin-based ETP proposals registered under the Investment Company Act of 1940 (the '' '40 Act''), ''particularly if those are limited to [the] CME-traded Bitcoin futures,'' noting the ''significant investor protection'' offered by the '40 Act.[44] In this same speech, the Chair specifically identified the Trust in the context of existing investment vehicles that provide exposure to Bitcoin, noting that the Trust, which is a Bitcoin-based ETP proposal that would be registered under the Securities Act of 1933 (the '' '33 Act''), rather than the '40 Act, is ''the largest among them having been around for eight years and worth more than $20 billion.'' [45]

As described above, the Commission has outlined the reasons why prior Bitcoin-based ETP proposals registered under both the '40 Act and '33 Act have been unable to satisfy its concerns about pricing in the underlying Digital Asset Market due to the potential for fraud and manipulation and described how such concerns could be addressed. It has been the Sponsor's understanding that none of the stated requirements have indicated a preference for Bitcoin-based ETP proposals registered under the '40 Act versus the '33 Act. Nor does the Sponsor believe that such requirements can be addressed by gaining exposure to Bitcoin through Bitcoin futures in an ETP registered under the '40 Act rather than physical Bitcoin in an ETP registered under the '33 Act because both products would be reliant on Bitcoin's underlying price in the spot markets.

For instance, Bitcoin-based ETP proposals registered under the '40 Act that hold Bitcoin futures would be priced by referencing the CME CF Bitcoin Reference Rate (''BRR''), which itself references the Digital Asset Markets: Bitstamp, Coinbase, Gemini, itBit, and Kraken. Similarly, Bitcoin-based ETPs that would be registered under the '33 Act, like the Trust, would be priced by referencing Digital Asset Markets included in the BRR, such as through the Index. As a result, the Sponsor believes that any potential fraud or manipulation in the underlying Digital Asset Market would impact both types of ETP proposals.

The Sponsor believes that if it is the case that the Commission is open to reviewing and potentially approving proposals for Bitcoin-based ETPs registered under the '40 Act, then it should take a similar view towards proposals for Bitcoin-based ETPs registered under the '33 Act, given that both products would be reliant on Bitcoin's underlying price in the spot markets. Alternatively, if this is not the case, the Sponsor nonetheless believes that the foregoing responds to the Commission's articulated concerns with respect to potential fraud and manipulation in Bitcoin-based ETPs.

Creation of Shares

According to the Annual Report, the Trust will issue Shares to Authorized Participants from time to time, but only in one or more Baskets (with a Basket being a block of 100 Shares). The Trust will not issue fractions of a Basket. The creation of Baskets will be made only in exchange for the delivery to the Trust, or the distribution by the Trust, of the number of whole and fractional Bitcoins represented by each Basket being created, which is determined by dividing (x) the number of Bitcoins owned by the Trust at 4:00 p.m., E.T., on the trade date of a creation order, after deducting the number of Bitcoins representing the U.S. dollar value of accrued but unpaid fees and expenses of the Trust (converted using the Index Price at such time, and carried to the eighth decimal place), by (y) the number of Shares outstanding at such time (with the quotient so obtained calculated to one one-hundred-millionth of one Bitcoin (*i.e.,* carried to the eighth decimal place)), and multiplying such quotient by 100 (the ''Basket Amount'').

[42] These Bitcoin spot markets include Binance, Coinbase Pro, Bitfinex, Kraken, Bitstamp, BitFlyer, Poloniex, Bittrex and itBit.

[43] To further illustrate the size and liquidity of the Trust, as of October 31, 2020, compared with global commodity ETPs, the Trust would rank fourth in assets under management and seventh in notional trading volume from November 1, 2019 to October 31, 2020.

[44] Chair Gary Gensler Public Statement, ''Remarks Before the Aspen Security Forum,'' (Aug. 3, 2021), *https://www.sec.gov/news/public-statement/gensler-aspen-security-forum-2021-08-03.*

[45] *Id.*

All questions as to the calculation of the Basket Amount will be conclusively determined by the Sponsor and will be final and binding on all persons interested in the Trust. The Basket Amount multiplied by the number of Baskets being created is the ''Total Basket Amount.'' The number of Bitcoins represented by a Share will gradually decrease over time as the Trust's Bitcoins are used to pay the Trust's expenses. As of June 30, 2021, each Share represented approximately 0.0009 of one Bitcoin.

Authorized Participants are the only persons that may place orders to create Baskets. Each Authorized Participant must (i) be a registered broker-dealer, (ii) enter into a Participant Agreement with the Sponsor and (iii) own a Bitcoin wallet address that is recognized by the Custodian as belonging to the Bitcoin wallet address that is known to the Custodian as belonging to the Authorized Participant. An Authorized Participant may act for its own account or as agent for broker-dealers, custodians and other securities market participants that wish to create or redeem Baskets. Shareholders who are not Authorized Participants will only be able to redeem their Shares through an Authorized Participant

The creation of Baskets requires the delivery to the Trust of the Total Basket Amount.

The Participant Agreement provides the procedures for the creation of Baskets and for the delivery of the whole and fractional Bitcoins required for such creations. The Participant Agreement and the related procedures attached thereto may be amended by the Sponsor and the relevant Authorized Participant. Under the Participant Agreement, the Sponsor has agreed to indemnify each Authorized Participant against certain liabilities, including liabilities under the Securities Act.

Authorized Participants do not pay a transaction fee to the Trust in connection with the creation of Baskets, but there may be transaction fees associated with the validation of the transfer of Bitcoins by the Bitcoin Network. Authorized Participants who deposit Bitcoins with the Trust in exchange for Baskets will receive no fees, commissions or other form of compensation or inducement of any kind from either the Sponsor or the Trust, and no such person has any obligation or responsibility to the Sponsor or the Trust to effect any sale or resale of Shares.

Creation Procedures

On any business day, an Authorized Participant may order one or more creation Baskets from the Trust by placing a creation order with the Sponsor no later than 4:00 p.m., New York time, which the Sponsor will accept or reject. By placing a creation order, an Authorized Participant agrees to transfer the Total Basket Amount from the Bitcoin wallet address that is known to the Custodian as belonging to the Authorized Participant to the Digital Asset Account.

All creation orders are accepted (or rejected) by the Sponsor on the business day on which the relevant creation order is placed. If a creation order is accepted, the Sponsor will calculate the Total Basket Amount on the same business day, which will be the trade date, and will communicate the Total Basket Amount to the Authorized Participant. The Authorized Participant must transfer the Total Basket Amount to the Trust no later than 6:00 p.m., E.T., on the trade date. The expense and risk of delivery, ownership and safekeeping of Bitcoins will be borne solely by the Authorized Participant until such Bitcoin have been received by the Trust.

Following receipt of the Total Basket Amount by the Custodian, the Trust's transfer agent (''Transfer Agent'') will credit the number of Shares to the account of the Investor on behalf of which the Authorized Participant placed the creation order by no later than 6:00 p.m., E.T., on the trade date.

Redemption of Shares

The Trust may redeem Shares from time to time but only in Baskets. A Basket equals a block of 100 Shares. The number of outstanding Shares is expected to decrease from time to time as a result of the redemption of Baskets. The redemption of Baskets requires the distribution by the Trust of the number of Bitcoins represented by the Baskets being redeemed. The redemption of a Basket will be made only in exchange for the distribution by the Trust of the number of whole and fractional Bitcoins represented by each Basket being redeemed, the number of which is determined by dividing (x) the number of Bitcoins owned by the Trust at 4:00 p.m., New York time, on the relevant trade date of a redemption order, after deducting the number of Bitcoins representing the U.S. dollar value of accrued but unpaid fees and expenses of the Trust (converted using the Index Price at such time, and carried to the eighth decimal place) by (y) the number of Shares outstanding at such time (with the quotient so obtained calculated to one one-hundred-millionth of one Bitcoin (*i.e.,* carried to the eighth decimal place)), and multiplying such quotient by 100.

Authorized Participants are the only persons that may place orders to redeem Baskets. Shareholders who are not Authorized Participants will be able to redeem their Shares only through an Authorized Participant.

Each Participant Agreement provides the procedures for the redemption of Baskets and for the delivery of the whole and fractional Bitcoins required for such redemption. The Participant Agreement and the related procedures attached thereto may be amended by the Sponsor and the relevant Authorized Participant.

Authorized Participants do not pay a transaction fee to the Trust in connection with the redemption of Baskets, but there may be transaction fees associated with the validation of the transfer of Bitcoins by the Bitcoin Network.

Redemption Procedures

On any business day, an Authorized Participant may place a redemption order no later than 4:00 p.m., New York time, which the Sponsor will accept or reject. By placing a redemption order, an Authorized Participant agrees to deliver to the Sponsor the Baskets to be redeemed through the book-entry system to the Trust. The redemption procedures do not allow a shareholder other than an Authorized Participant to redeem Shares. All redemption orders are accepted (or rejected) by the Sponsor on the business day on which the relevant redemption order is placed. If a redemption order is accepted, the Sponsor will calculate the Total Basket Amount on the same business day, which will be the trade date, and will communicate the Total Basket Amount to the Authorized Participant. The Sponsor will then direct the Transfer Agent to debit the account of the Authorized Participant the number of Baskets ordered no later than 6:00 p.m., New York time, on the trade date.

Following receipt of confirmation by the Transfer Agent that the Baskets have been debited, the Sponsor or its delegates will instruct the Custodian to send the Authorized Participant the Total Basket Amount by no later than 6:00 p.m., New York time, on the trade date.

The redemption of Shares may be suspended generally, or refused with respect to particular requested redemptions, during any period when the transfer books of the Transfer Agent are closed or if circumstances outside the control of the Sponsor or its delegates make it for all practical purposes not feasible to process such redemption orders. The Sponsor may reject an order or, after accepting an

order, may cancel such order by rejecting the Baskets to be redeemed if (i) such order is not presented in proper form as described in the Participant Agreement or (ii) the fulfillment of the order, in the opinion of counsel, might be unlawful, among other reasons. None of the Sponsor or its delegates will be liable for the suspension, rejection or acceptance of any redemption order. In particular, upon the Trust's receipt of any Incidental Rights and/or IR Virtual Currency in connection with a fork, airdrop or similar event, the Sponsor may suspend redemptions until it is able to cause the Trust to sell or distribute such Incidental Rights and/or IR Virtual Currency.

Availability of Information

The Trust's website (*https://grayscale.com/products/grayscale-bitcoin-trust/*) will include quantitative information on a per Share basis updated on a daily basis, including, (i) the current Digital Asset Holdings per Share daily and the prior business day's Digital Asset Holdings and the reported closing price; (ii) the mid-point of the bid-ask price [46] in relation to the Digital Asset Holdings as of the time the Digital Asset Holdings is calculated (''Bid-Ask Price'') and a calculation of the premium or discount of such price against such Digital Asset Holdings; and (iii) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid-Ask Price against the Digital Asset Holdings, within appropriate ranges, for each of the four previous calendar quarters (or for the life of the Trust, if shorter). In addition, on each business day the Trust's website will provide pricing information for the Shares.

The Trust's website, as well as one or more major market data vendors, will provide an intra-day indicative value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third party financial data provider during the Exchange's Core Trading Session (9:30 a.m. to 4:00 p.m., E.T.).[47] The IIV will be calculated using the same methodology as the Digital Asset Holdings of the Trust (as described above), specifically by using the prior day's closing Digital Asset Holdings per Share as a base and updating that value during the NYSE Arca Core Trading Session to reflect changes in the value of the Trust's Digital Asset Holdings during the trading day.

The IIV disseminated during the NYSE Arca Core Trading Session should not be viewed as an actual real-time update of the Digital Asset Holdings, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The Digital Asset Holdings for the Trust will be calculated by the Sponsor once a day and will be disseminated daily to all market participants at the same time. To the extent that the Sponsor has utilized the cascading set of rules described in ''Index Price'' above, the Trust's website will note the valuation methodology used and the price per Bitcoin resulting from such calculation. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

Quotation and last sale information for Bitcoin will be widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. In addition, the complete real-time price (and volume) data for Bitcoin is available by subscription from Reuters and Bloomberg. The spot price of Bitcoin is available on a 24-hour basis from major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, in Bitcoin will be available from major market data vendors and from the exchanges on which Bitcoin are traded. The normal trading hours for Digital Asset Exchanges are 24-hours per day, 365-days per year.

The Sponsor will publish the Index Price, the Trust's Digital Asset Holdings, and the Digital Asset Holdings per Share on the Trust's website as soon as practicable after its determination. If the Digital Asset Holdings and Digital Asset Holdings per Share have been calculated using a price per Bitcoin other than the Index Price for such Evaluation Time, the publication on the Trust's website will note the valuation methodology used and the price per Bitcoin resulting from such calculation.

The Trust will provide website disclosure of its Digital Asset Holdings daily. The website disclosure of the Trust's Digital Asset Holdings will occur at the same time as the disclosure by the Sponsor of the Digital Asset Holdings to Authorized Participants so that all market participants are provided such portfolio information at the same time. Therefore, the same portfolio information will be provided on the public website as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current Digital Asset Holdings of the Trust through the Trust's website, as well as from one or more major market data vendors.

The value of the Index, as well as additional information regarding the Index, may be found at *https://tradeblock.com/markets/index/xbx.*

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m., E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.201–E. The trading of the Shares will be subject to NYSE Arca Rule 8.201–E(g), which sets forth certain restrictions on Equity Trading Permit (''ETP'') Holders acting as registered Market Makers in Commodity-Based Trust Shares to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Trust will be in compliance with Rule 10A–3 [48] under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 100,000 Shares of the Trust will be outstanding at the commencement of trading on the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Trust.[49] Trading in Shares of the Trust will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the

[46] The bid-ask price of the Trust is determined using the highest bid and lowest offer on the Consolidated Tape as of the time of calculation of the closing day Digital Asset Holdings.

[47] The IIV on a per Share basis disseminated during the Core Trading Session should not be viewed as a real-time update of the Digital Asset Holdings, which is calculated once a day.

[48] 17 CFR 240.10A–3.

[49] *See* NYSE Arca Rule 7.12–E.

Exchange, make trading in the Shares inadvisable.

The Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of the Index occurs. If the interruption to the dissemination of the IIV or the value of the Index persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the Digital Asset Holdings per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the Digital Asset Holdings per Share is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares of the Trust will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[50] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[51] The Exchange is also able to obtain information regarding trading in the Shares in connection with such ETP Holders' proprietary or customer trades which they effect through ETP Holders on any relevant market.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolios of the Trust, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The Sponsor has represented to the Exchange that it will advise the Exchange of any failure by the Trust to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Trust is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an ''Information Bulletin'' of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The procedures for creations of Shares in Baskets; (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) information regarding how the value of the Index and the IIV are disseminated; (4) the possibility that trading spreads and the resulting premium or discount on the Shares may widen during the Opening and Late Trading Sessions, when an updated IIV will not be calculated or publicly disseminated; and (5) trading information. The Exchange notes that investors purchasing Shares directly from the Trust will receive a prospectus.

In addition, the Information Bulletin will reference that the Trust is subject to various fees and expenses as described in the Annual Report. The Information Bulletin will disclose that information about the Shares of the Trust is publicly available on the Trust's website.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[52] that an exchange have rules that are 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, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets. In addition, the Exchange may obtain information regarding trading in the Shares from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Rule 8.201–E(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying Bitcoin or any Bitcoin derivative through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The proposed rule change is also designed to prevent fraudulent and manipulative acts and practices because, although the Digital Asset Exchange Market is not inherently resistant to fraud and manipulation, the Index serves as a means sufficient to mitigate the impact of instances of fraud and manipulation on a reference price for Bitcoin. Specifically, the Index provides a better benchmark for the

[50] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[51] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Trust may trade on markets that are members of ISG or with which the Exchange has in place a CSSA.

[52] 15 U.S.C. 78f(b)(5).

price of Bitcoin than the Digital Asset Exchange Market Price because it (1) tracks the Digital Asset Exchange Market Price through trading activity at U.S.-Compliant Exchanges; (2) mitigates the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments; (3) is constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events; (4) mitigates the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific exchange through a cross-exchange composite index rate; and (5) mitigates the impact of instances of fraud, manipulation and other anomalous trading activity occurring on multiple exchanges by using a 24-hour window to weight the activity at each exchange through a VWAP. The Trust has used the Index to price the Shares for more than six years, and the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the Bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of bitcoin and (iii) appropriately handle and adjusts for non-market related events, such that efforts to manipulate the price of Bitcoin would have had a negligible effect on the pricing of the Trust, due to the controls embedded in the structure of the Index. In addition, certain of the Index's Constituent Exchanges also have or have begun to implement market surveillance infrastructure to further detect, prevent, and respond to fraud, attempted fraud, and similar wrongdoing, including market manipulation. The proposed rule change is also designed to prevent fraudulent and manipulative acts and practices based on the existence of the CME futures market as a large, surveilled and regulated market that is closely connected with the spot market for Bitcoin and through which the Exchange could obtain information to assist in detecting and deterring potential fraud or manipulation.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of Bitcoin price and market information available on public websites and through professional and subscription services. Investors may obtain, on a 24-hour basis, Bitcoin pricing information based on the spot price for Bitcoin from various financial information service providers. The closing price and settlement prices of Bitcoin are readily available from the Digital Asset Exchanges and other publicly available websites. In addition, such prices are published in public sources, or on-line information services such as Bloomberg and Reuters. The Digital Asset Holdings per Share will be calculated daily and made available to all market participants at the same time. The Trust will provide website disclosure of its Digital Asset Holdings daily. One or more major market data vendors will disseminate for the Trust on a daily basis information with respect to the most recent Digital Asset Holdings per Share and Shares outstanding. In addition, if the Exchange becomes aware that the Digital Asset Holdings per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the Digital Asset Holdings is available to all market participants. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session (normally 9:30 a.m., E.T., to 4:00 p.m., E.T.) by one or more major market data vendors. In addition, the IIV will be available on the Trust's website through on-line information services. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of the Index occurs. If the interruption to the dissemination of the IIV or the value of the Index persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as noted above, investors will have ready access to information regarding the Trust's Digital Asset Holdings, IIV, and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product, and the first such product based on Bitcoin, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–90 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–90. This file number should be included on the subject line if email is used. To help the Commission process and review your

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–90 and should be submitted on or before November 29, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24323 Filed 11–5–21; 8:45 am]

BILLING CODE 8011–01–P

[53] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93510; File No. SR-CboeBZX–2021–051]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change to List and Trade Shares of the ARK 21Shares Bitcoin ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

November 2, 2021.

On July 20, 2021, Cboe BZX Exchange, Inc. (''BZX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the ARK 21Shares Bitcoin ETF (''Trust'') under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on August 6, 2021.[3]

On September 15, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] This order institutes proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.

I. Summary of the Proposal

As described in more detail in the Notice,[7] the Exchange proposes to list and trade the Shares of the Trust under BZX Rule 14.11(e)(4), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust would be to seek to track the performance of bitcoin, as measured by the performance of the S&P Bitcoin Index (''Index''), adjusted for the Trust's expenses and other liabilities.[8] Each Share will represent a fractional undivided beneficial interest in the bitcoin held by the Trust. The Trust's assets will consist of bitcoin held by the Custodian on behalf of the Trust. The Trust generally does not intend to hold cash or cash equivalents. However, there may be situations where the Trust will unexpectedly hold cash on a temporary basis.[9]

In seeking to achieve its investment objective, the Trust would hold bitcoin and would value the Shares daily based on the Index. The Index is a U.S. dollar-denominated composite reference rate for the price of bitcoin. The current platform composition of the Index is Binance, Bitfinex, Bitflyer, Bittrex, Bitstamp, Coinbase Pro, Gemini, HitBTC, Huobi, Kraken, KuCoin, and Poloniex.[10] The Index methodology is intended to determine the fair market value for bitcoin by determining the principal market for bitcoin as of 4:00 p.m. E.T. daily.[11]

The Net Asset Value (''NAV'') of the Trust means the total assets of the Trust including, but not limited to, all bitcoin and cash, if any, less total liabilities of the Trust, each determined on the basis of generally accepted accounting principles. The NAV of the Trust is the aggregate value of the Trust's assets less its estimated accrued but unpaid liabilities (which include accrued expenses). In determining the Trust's NAV, the Administrator values the bitcoin held by the Trust based on the price set by the Index as of 4:00 p.m. E.T. The Administrator determines the NAV of the Trust on each day that the Exchange is open for regular trading, as promptly as practical after 4:00 p.m. E.T.[12]

The Trust will provide information regarding the Trust's bitcoin holdings, as well as an Intraday Indicative Value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. E.T. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 92543 (Aug. 2, 2021), 86 FR 43289 (''Notice''). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-cboebzx-2021-051/srcboebzx2021051.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92989, 86 FR 52530 (Sept. 21, 2021). The Commission designated November 4, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Notice, *supra* note 3.

[8] *See id.* at 43298. 21SharesUS LLC (''Sponsor'') is the sponsor of the Trust, Delaware Trust Company is the trustee, The Bank of New York Mellon will be the administrator and transfer agent. Foreside Global Services, LLC will be the marketing agent in connection with the creation and redemption of Shares. ARK Investment Management LLC will provide assistance in the marketing of the Shares. Coinbase Custody Trust Company, LLC (''Custodian''), will be responsible for custody of the Trust's bitcoin. *See id.* at 43290, 43297.

[9] *See id.* at 43297.

[10] The underlying platforms are sourced by Lukka Inc. (''Data Provider'') based on a combination of qualitative and quantitative metrics to analyze a comprehensive data set and evaluate factors including legal/regulation, Know-Your-Customer/transaction risk, data provision, security, team/exchange, asset quality/diversity, market quality and negative events. *See id.* at 43298.

[11] The Index methodology uses a ranking approach that considers several exchange characteristics including oversight and intra-day trading volume. Specifically, to rank the credibility and quality of each exchange, the Data Provider dynamically assigns a Base Exchange Score (''BES'') score to the key characteristics for each exchange. The BES reflects the fundamentals of an exchange and determines which exchange should be designated as the principal market at a given point of time. This score is determined by computing a weighted average of the values assigned to four different exchange characteristics: (i) oversight; (ii) microstructure efficiency; (iii) data transparency; and (iv) data integrity. The methodology then applies a five-step weighting process for identifying a principal exchange and the last price on that exchange. Following this weighting process, an executed exchange price is assigned for bitcoin as of 4:00 p.m. E.T. *See id.*

[12] *See id.* at 43299.

base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's bitcoin holdings during the trading day.[13]

When the Trust sells or redeems its Shares, it will do so in ''in-kind'' transactions in blocks of 5,000 Shares. Authorized participants will deliver, or facilitate the delivery of, bitcoin to the Trust's account with the Custodian in exchange for Shares when they purchase Shares, and the Trust, through the Custodian, will deliver bitcoin to such authorized participants when they redeem Shares with the Trust.[14]

II. Proceedings to Determine Whether to Approve or Disapprove SR–CboeBZX–2021–051 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[15] to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change, as discussed below. 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 comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[16] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with 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'' and ''to protect investors and the public interest.''[17]

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[18] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. What are commenters' views on whether the proposed Trust and Shares would be susceptible to manipulation? What are commenters' views generally on whether the Exchange's proposal is designed to prevent fraudulent and manipulative acts and practices? What are commenters' views generally with respect to the liquidity and transparency of the bitcoin markets, the bitcoin markets' susceptibility to manipulation, and thus the suitability of bitcoin as an underlying asset for an exchange-traded product?

2. What are commenters' views of the Exchange's assertion that the regulatory and financial landscapes relating to bitcoin and other digital assets have changed significantly since 2016?[19] Are the changes that the Exchange identifies sufficient to support the determination that the proposal to list and trade the Shares is designed to protect investors and the public interest and is consistent with the other applicable requirements of Section 6(b)(5) of the Act?

3. The Exchange states that ''approving this proposal . . . [would] allow U.S. investors with access to bitcoin in a regulated and transparent exchange-traded vehicle that would act to limit risk'' associated with exposure through other means.[20] Further, the Exchange asserts that ''the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.''[21] What are commenters' views regarding such assertions?

4. According to the Exchange, ''[n]early every measurable metric related to [Chicago Mercantile Exchange's] Bitcoin Futures has trended consistently up since launch and/or accelerated upward in the past year.''[22] Based on data provided and the academic research cited by the Exchange, do commenters agree that the Chicago Mercantile Exchange (''CME'')'s bitcoin futures market now represents a regulated market of significant size?[23] What are commenters' views on whether there is a reasonable likelihood that a person attempting to manipulate the Shares would also have to trade on CME to manipulate the Shares? What are commenters' views on the Exchange's assertion that the combination of (a) CME bitcoin futures leading price discovery; (b) the overall size of the bitcoin market; and (c) the ability for market participants to buy or sell large amounts of bitcoin without significant market impact would help to prevent the Shares from becoming the predominant force on pricing in either the bitcoin spot or CME bitcoin futures markets?[24]

5. What are commenters' views on the Exchange's statement, generally, that bitcoin is resistant to price manipulation and that other means to prevent fraudulent and manipulative acts and practices exist to justify dispensing with the requisite surveillance sharing agreement with a regulated market of significant size related to bitcoin?[25] What are commenters' views on the Exchange's assertion in support of such statement that significant liquidity in the spot market and the impact of market orders on the overall price of bitcoin mean that attempting to move the price of bitcoin is costly?[26] What are commenters' views on the assertion that offering only in-kind creations and redemptions provides unique protections against potential attempts to manipulate the Shares and that the price the Sponsor uses to value the Trust's bitcoin ''is not particularly important''?[27]

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[28]

[13] *See id.*

[14] *See id.* at 43297–98.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] *Id.*

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Notice, *supra* note 3.

[19] *See id.* at 43291–92.

[20] *See id.* at 43292.

[21] *See id.* at 43296.

[22] *See id.* at 43294.

[23] *See id.* at 43291, 43294–96.

[24] *See id.* at 43297.

[25] *See id.* at 43296 n.54.

[26] *See id.* at 43297.

[27] *See id.*

[28] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Pub. L. 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm.

Continued

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by November 29, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by December 13, 2021.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2021–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2021–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2021–051 and should be submitted by November 29, 2021. Rebuttal comments should be submitted by December 13, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24326 Filed 11–5–21; 8:45 am]

BILLING CODE 8011–01–P

[29] 17 CFR 200.30–3(a)(57).

on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

SMALL BUSINESS ADMINISTRATION

Delegation of Authority

AGENCY: U.S. Small Business Administration.

ACTION: Notice of delegation of authority.

SUMMARY: This document provides the public with notice of the delegation of authority for certain activities related to the licensing of small business investment companies by the Administrator of the U.S. Small Business Administration (SBA) to the Agency SBIC Licensing Committee.

FOR FURTHER INFORMATION CONTACT: Arthur Spivey, Office of Investment and Innovation, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416; (202) 205–7098 or *arthur.spivey@sba.gov.*

SUPPLEMENTARY INFORMATION: This document provides the public with notice of the Administrator's delegation of authority to the Agency SBIC Licensing Committee to review and recommend to the Administrator for approval applications for licenses to operate as a small business investment company under the Small Business Investment Act of 1958, as amended.

This delegation of authority reads as follows:

Pursuant to the authority vested in me pursuant to section 301 of the Small Business Investment Act of 1958, as amended, the authority to take any and all actions necessary to review applications for licensing under section 301 of the Small Business Investment Act of 1958, as amended, and to recommend to the Administrator which such applications should be approved is delegated to the Agency SBIC Licensing Committee (as defined in SBA Standard Operating Procedure 10 04 01, effective Aug. 6, 2014, *Processing Applications for SBIC Licenses*).

The Agency SBIC Licensing Committee shall be composed of the following members:

Chief of Staff, Chair
Associate Administrator for Capital Access
Associate Administrator for Investment and Innovation
General Counsel
Deputy General Counsel
Chief Financial Officer

This authority revokes all other authorities granted by the Administrator to recommend and approve applications for a license to operate as a small business investment company under the Small Business Investment Act of 1958, as amended. This authority may not be re-delegated; however, in the event that the person serving in one of the positions listed as a member of the Agency SBIC Licensing Committee is absent from the office, as defined in SBA Standard Operating Procedure 00 01 3 (effective April 17, 2018), Chapter VI.B., or is unable to perform the functions and duties of his or her position, the individual serving in an acting capacity, pursuant to a written and established line of succession, may serve on the Committee during such absence or inability. In addition, if one of the positions listed as a member of the Agency SBIC Licensing Committee is vacant, the individual serving in that position in an acting capacity shall serve on the Agency SBIC Licensing Committee. This authority will remain in effect until revoked in writing by the Administrator or by operation of law.

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2021–24344 Filed 11–5–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 11579]

Privacy Act of 1974; System of Records

ACTION: Notice of a modified system of records.

SUMMARY: This system of records compiles information used in the adjudication of U.S. visas.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice is applicable upon publication.

ADDRESSES: Questions can be submitted by mail, email, or by calling Eric F. Stein, the Senior Agency Official for Privacy, on (202) 485–2051. If mail, please write to: U.S. Department of State; Office of Global Information Systems, A/GIS; Room 1417, 2201 C St. NW, Washington, DC 20520. If email, please address the email to the Senior Agency Official for Privacy, Eric F. Stein, at *Privacy@state.gov.* Please write ''Visa Records, State–39'' on the envelope or the subject line of your email.

FOR FURTHER INFORMATION CONTACT: Eric F. Stein, Senior Agency Official for Privacy; U.S. Department of State; Office of Global Information Services, A/GIS; Room 1417, 2201 C St. NW, Washington, DC 20520 or by calling (202) 485–2051.

SUPPLEMENTARY INFORMATION: The purpose of this modification is to make substantive and administrative changes to the previously published notice. This notice modifies the following sections of State–39, Visa Records: System Location, Categories of Individuals Covered by the System, Categories of Records in the System, Record Source Categories, and Administrative, Technical, and Physical Safeguards. In addition, this notice makes administrative updates to the following sections: Record Access Procedures, Contesting Record Procedures, Notification Procedures, and History. These changes reflect new visa adjudication procedures, the movement to cloud storage, updated contact information, and a notice publication history.

SYSTEM NAME AND NUMBER:

Visa Records, State–39.

SECURITY CLASSIFICATION:

Unclassified and Classified.

SYSTEM LOCATION:

Department of State (''Department''), located at 2201 C St. NW, Washington, DC 20520; Visa Office, Department of State, Annex 17, 600 19th St. NW, Washington, DC 20006; National Visa Center, 32 Rochester Avenue, Portsmouth, NH 03801; Kentucky Consular Center, 3505 N. U.S. Hwy 25 W., Williamsburg, KY 40769; U.S. embassies, consulates general, consulates, and Department of State Enterprise Server Operations Centers (henceforth referred to as the Department of State). Records may also be located within a government-certified cloud provided by a cloud-based service provider.

SYSTEM MANAGER(S):

Deputy Assistant Secretary for Visa Services, Room 6811, Department of State, 2201 C St. NW, Washington, DC 20520–4818; Director, National Visa Center, 32 Rochester Avenue, Portsmouth, NH 63801; Director, Kentucky Consular Center, 3505 N. U.S. Hwy 25 W., Williamsburg, KY 40769. All system managers can be contacted with this email address *PRA_BurdenComments@state.gov.* When emailing system managers, include the phrase ''SORN'' in the email subject line. At specific locations abroad, the on-site manager is the consular officer responsible for visa processing.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 (Secretary of State's authorities with respect to Management of the Department of State); 22 U.S.C. 2651a (Organization of the Department of State); 22 U.S.C. 3921 (Management of the Foreign Service); 8 U.S.C. 1101–1537 (Immigration and Nationality Act of 1952, as amended).

PURPOSE(S) OF THE SYSTEM:

The Visa Records system maintains information used to assist the Bureau of Consular Affairs and consular officers in the Department and abroad in adjudicating visas and Certificates of Identity. It is also used in dealing with problems of a legal, enforcement, technical, or procedural nature that may arise in connection with a U.S. visa or Certificate of Identity.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Visa Records may include the following individuals when required by a visa application or a Certificate of Identity application: U.S. petitioners, U.S. persons applying for returning residence travel documentation, and visa and Certificate of Identity applicants who subsequently become documented as U.S. persons. The Privacy Act defines an individual at 5 U.S.C. 552a(a)(2) as a U.S. citizen or lawful permanent resident.

CATEGORIES OF RECORDS IN THE SYSTEM:

Visa Records maintains visa applications and related forms; Certificate of Identity applications or portions thereof; documents of identity; biometric information; social security numbers; national identity numbers; photographs; financial information; gender, birth, marriage, death and divorce certificates; interview worksheets; biographic information sheets; affidavits of relationship; medical examinations and immunization reports; police records, criminal and legal information; educational and employment records; petitions for immigrant status and nonimmigrant status; bank statements; social media handles and information gathered from social media; communications between the Visa Office, the National Visa Center, the Kentucky Consular Center, U.S. embassies, U.S. consulates general and U.S. consulates, other U.S. government agencies, international organizations, members of Congress, legal and other representatives of visa applicants, relatives of visa applicants, and other interested parties where such communications are, or may be, relevant to visa adjudication; and internal Department of State correspondence and notes relating to visa adjudication. Visa Records may also contain information collected regarding applicants' or petitioners' U.S. family members; U.S. employers; and other U.S. persons referenced by the applicant or petitioner.

RECORD SOURCE CATEGORIES:

These records contain information that is primarily obtained from the individual who is the subject of the records; attorneys/agents representing these individuals; relatives; sponsors; petitioners; members of Congress; U.S. Government agencies; foreign government agencies, international organizations; local sources at posts; and anyone else with information that is, or may be, relevant to a U.S. visa application.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The principal users of this information outside the Department of State may include, when consistent with Section 222(f) of the Immigration and Nationality Act:

A. The Department of Homeland Security for uses within its statutory mission, including to process, approve or deny visa petitions and waivers, as well as for law enforcement, counterterrorism, transportation and border security, administration of immigrant benefits, critical infrastructure protection, fraud prevention, or employment verification purposes.

B. Public or private employers seeking to confirm the authenticity of the visa when it is presented as evidence of identity and/or authorization to work in the United States;

C. The Department of Justice, including the Federal Bureau of Investigation (and its National Crime Information Center), the Terrorist Screening Center, the Bureau of Alcohol, Tobacco, Firearms and Explosives, the U.S. National Central Bureau (Interpol) and the Drug Enforcement Administration, for purposes of law enforcement, criminal prosecution, representation of the U.S. government in civil litigation, fraud prevention, counterterrorism, or border security.

D. The Department of the Treasury for uses within its statutory mission, including the enforcement of U.S. tax laws, economic sanctions, and counterterrorism.

E. The National Counterterrorism Center, the Office of the Director of

National Intelligence and other U.S. intelligence community (IC) agencies, for uses within their statutory missions, including intelligence, counterintelligence, counterterrorism and other national security interests.

F. The Department of Defense, for uses within its statutory mission including for purposes of border security, homeland defense, force protection, law enforcement and counterterrorism.

G. The Department of Labor for uses within its statutory mission including the administration and enforcement of U.S. labor laws.

H. Congress, for the formulation, amendment, administration, or enforcement of the immigration, nationality, and other laws of the United States.

I. State, local, and tribal government officials for law enforcement, counterterrorism, or border security purposes.

J. Interested persons (such as the visa applicant, the applicant's legal representative or other designated representative) inquiring as to the status of a particular visa case (limited unclassified information may be released when appropriate).

K. Courts provided the Secretary of State has determined that release is appropriate, and the court has certified it needs such information in the interest of the ends of justice in a case pending before the court.

L. Foreign governments for purposes relating to the administration or enforcement of the immigration, nationality, and other laws of the United States, or in the Secretary's discretion and on the basis of reciprocity, for the purpose of preventing, investigating, or punishing acts that would constitute a crime in the United States or, pursuant to an agreement with a foreign government, to enable such government to consider whether the record indicates a person would be inadmissible to the United States when it determines whether to deny a visa, grant entry, authorize an immigration benefit, or order removal of such person.

M. The Centers for Disease Control and Prevention, for uses within its statutory mission, including its role relative to the physical and mental examination of aliens under immigration laws.

N. Appropriate agencies, entities, and persons when (1) the Department of State suspects or has confirmed that there has been a breach of the system of records; (2) the Department of State has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department of State (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 the Department of State efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

O. Another Federal agency or Federal entity, when the Department of State 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.

The Department of State periodically publishes in the **Federal Register** its standard routine uses that apply to all of its Privacy Act systems of records. These notices appear in the form of a Prefatory Statement (published in Volume 73, Number 136, Public Notice 6290, on July 15, 2008). All these standard routine uses apply to Visa Records, State–39.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored both in hard copy and on electronic media. A description of standard Department of State policies concerning storage of electronic records is found in the Department's Foreign Affairs Manual (*https://fam.state.gov/FAM/05FAM/05FAM0440.html*). All hard copies of records containing personal information are maintained in secured file cabinets in restricted areas, access to which is limited to authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved through individual data fields including but not limited to: Applicant personal data; biometrics and namecheck data; case data; and visa data.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The retention period for visa records depends on the nature of the information and disposition of the visa adjudication. Some files related to issued immigrant visas are destroyed six months after issuance. In some instances, files with historical significance are permanent records. Most files related to Certificates of Identity are retained for twenty-five years after closure. These records are retired and destroyed in accordance with published Department of State Records Disposition Schedules as approved by the National Archives and Records Administration (NARA), and a complete list of the Department's schedules can be found on its Freedom of Information Act (FOIA) program's website (*https://foia.state.gov/Learn/RecordsDisposition.aspx*). More specific information may be obtained by writing to the following address: U.S. Department of State; Director, Office of Information Programs and Services; A/GIS/IPS; 2201 C Street NW; Room B–266; Washington, DC 20520.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All Department of State network users are given cyber security awareness training which covers the procedures for handling Sensitive but Unclassified information, including personally identifiable information (PII). Annual refresher training is mandatory. In addition, all Department OpenNet network users are required to take the Foreign Service Institute's distance learning course instructing employees on privacy and security requirements, including the rules of behavior for handling PII and the potential consequences if it is handled improperly. Before being granted access to Visa Records, a user must first be granted access to the Department of State network system.

Department of State employees and contractors may remotely access this system of records using non-Department owned information technology. Such access is subject to approval by the Department's mobile and remote access program and is limited to information maintained in unclassified information systems. Remote access to the Department's information systems is configured in compliance with the Office of Management and Budget Circular Memorandum A–130 multifactor authentication requirements and includes a time-out function.

All Department of State employees and contractors with authorized access to records maintained in this system of records have undergone a background security investigation. Access to the Department of State, its annexes and posts abroad is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. While the majority of records covered in Visa Records are electronic, all paper records containing personal information are maintained in secured file cabinets in restricted areas,

access to which is limited to authorized personnel only. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage. When it is determined that a user no longer needs access, the user account is disabled.

The safeguards in the following paragraphs apply only to records that are maintained in government-certified cloud systems. All cloud systems that provide IT services and process Department of State personally identifiable information (PII) must be specifically authorized by the Department of State Authorizing Official and Senior Agency Official for Privacy.

Information that conforms with Department-specific definitions for FISMA low, moderate, or high categorization are permissible for cloud usage and must specifically be authorized by the Department's Cloud Management Office and the Department of State Authorizing Official. Specific security measures and safeguards will depend on the FISMA categorization of the information in a given cloud system. In accordance with Department policy, systems that process more sensitive information will require more stringent controls and review by Department cybersecurity experts prior to approval. Prior to operation, all Cloud systems must comply with applicable security measures that are outlined in FISMA, FedRAMP, OMB regulations, National Institute of Standards and Technology (NIST) Special Publications (SP) and Federal Information Processing Standards (FIPS) and Department of State policies and standards.

All data stored in cloud environments categorized above a low FISMA impact risk level must be encrypted at rest and in-transit using a federally-approved encryption mechanism. The encryption keys shall be generated, maintained, and controlled in a Department data center by the Department key management authority. Deviations from these encryption requirements must be approved in writing by the Department of State Authorizing Official. High FISMA impact risk level systems will additionally be subject to continual auditing and monitoring, multifactor authentication mechanisms utilizing Public Key Infrastructure (PKI) and NIST 800–53 controls concerning virtualization, servers, storage and networking, as well as stringent measures to sanitize data from the cloud service once the contract is terminated.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to or to amend records pertaining to themselves should write to U.S. Department of State; Director, Office of Information Programs and Services; A/GIS/IPS; 2201 C St. NW; Room B–266; Washington, DC 20520. The individual must specify that he or she wishes the Visa Records to be checked. At a minimum, the individual must include: Full name (including maiden name, if appropriate) and any other names used; current mailing address and zip code; date and place of birth; email address; telephone number; notarized signature or statement under penalty of perjury; a brief description of the circumstances that caused the creation of the record (including the city and/or country and the approximate dates) which gives the individual cause to believe that the Visa Records include records pertaining to the individual. Detailed instructions on Department of State procedures for accessing and amending records can be found at the Department's FOIA website (*https://foia.state.gov/Request/Guide.aspx*).

However, in general, visa records are confidential and may not be released under section 222(f) of the Immigration and Nationality Act, except that, the Department of State may consider requests for records that originated with, or were sent to, a requesting visa applicant or someone acting on such applicant's behalf to be releasable thereto.

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest record procedures should write to U.S. Department of State; Director, Office of Information Programs and Services; A/GIS/IPS; 2201 C St. NW; Room B–266; Washington, DC 20520.

NOTIFICATION PROCEDURES:

Individuals who have reason to believe that this system of records may contain information pertaining to them may write to U.S. Department of State; Director, Office of Information Programs and Services; A/GIS/IPS; 2201 C St. NW; Room B–266; Washington, DC 20520. The individual must specify that he or she wishes the Visa Records to be checked. At a minimum, the individual must include: Full name (including maiden name, if appropriate) and any other names used; current mailing address and zip code; date and place of birth; email address; telephone number; notarized signature or statement under penalty of perjury; a brief description of the circumstances that caused the creation of the record (including the city and/or country and the approximate dates) which gives the individual cause to believe that the Visa Records include records pertaining to the individual.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(3), records contained within this system of records are exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f). See Department of State Rules published in the **Federal Register**, under 22 CFR 171.26.

HISTORY:

This SORN was previously published at 83 FR 28062 (June 15, 2018).

Eric F. Stein,

Acting Deputy Assistant Secretary, Bureau of Administration, Global Information Services, U.S. Department of State.

[FR Doc. 2021–24303 Filed 11–5–21; 8:45 am]

BILLING CODE 4710–13–P

DEPARTMENT OF STATE

[Public Notice: 11574]

Certification of Mexico

ACTION: Notice of country certification.

SUMMARY: On October 21, 2021, the Department of State certified to Congress that Mexico's turtle excluder device (TED) program was determined to again be comparable to the United States program. Wild-caught shrimp harvested in Mexico is again eligible to enter the United States in accordance with Section 609(b)(2)(A) and (B).

FOR FURTHER INFORMATION CONTACT: Jared Milton, Section 609 Program Manager, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, 2201 C Street NW, Washington, DC 20520–2758; telephone: (202) 647–3263; email: *DS2031@state.gov.*

SUPPLEMENTARY INFORMATION: Section 609 of Public Law 101–162 (''Sec. 609'') prohibits imports of wild-caught shrimp or products from shrimp harvested with commercial fishing technology unless the President certifies to the Congress by May 1, 1991, and annually thereafter, that either: (1) The harvesting nation has adopted a regulatory program governing the incidental taking of relevant species of sea turtles in the course of commercial shrimp harvesting that is comparable to that of the United States and that the average rate of that incidental taking by the vessels of the harvesting nation is comparable to the average rate of incidental taking of sea turtles by United States vessels in the course of such harvesting; or (2) the

particular fishing environment of the harvesting nation does not pose a threat of the incidental taking of sea turtles in the course of shrimp harvesting. The President has delegated the authority to make this certification to the Secretary of State (''Secretary'') who further delegated the authority within the Department of State (''Department''). The Revised Guidelines for the Implementation of Sec. 609 were published in the **Federal Register** on July 8, 1999, at 64 FR 36946.

The Department suspended the certification of Mexico, effective May 1, 2021, because its sea turtle protection program was no longer comparable to that of the United States. The Government of Mexico subsequently implemented a plan of action to strengthen sea turtle conservation in its shrimp trawl fisheries, resulting in significantly improved use of turtle excluder devices by its fishing industry, as verified by a team of representatives from the Department and the National Marine Fisheries Service. The Department has now certified Mexico under Sec. 609(b)(2)(A) and (B).

The Department has communicated this decision under Sec. 609 to the Office of Trade of U.S. Customs and Border Protection.

Constance Arvis,

Deputy Assistant Secretary for Oceans, Fisheries, and Polar Affairs, Department of State.

[FR Doc. 2021–24210 Filed 11–5–21; 8:45 am]

BILLING CODE 4710–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36500]

Canadian Pacific Railway Limited; Canadian Pacific Railway Company; Soo Line Railroad Company; Central Maine & Quebec Railway US Inc.; Dakota, Minnesota & Eastern Railroad Corporation; and Delaware & Hudson Railway Company, Inc.—Control—Kansas City Southern; The Kansas City Southern Railway Company; Gateway Eastern Railway Company; and The Texas Mexican Railway Company

AGENCY: Surface Transportation Board.

ACTION: Decision No. 9 in Docket No. FD 36500; notice of proposed procedural schedule and request for comments.

SUMMARY: The Surface Transportation Board (Board) invites public comments on a proposed procedural schedule for this proceeding. On September 15, 2021, Canadian Pacific Railway Limited (Canadian Pacific), Canadian Pacific Railway Company, and their U.S. rail carrier subsidiaries, Soo Line Railroad Company, Central Maine & Quebec Railway US Inc., Dakota, Minnesota & Eastern Railroad Corporation, and Delaware & Hudson Railway Company, Inc. (collectively, CP) and Kansas City Southern and its U.S. rail carrier subsidiaries, The Kansas City Southern Railway Company (KCSR), Gateway Eastern Railway Company, and The Texas Mexican Railway Company (collectively, KCS) (CP and KCS collectively, Applicants) filed an amended notice of intent to file an application seeking authority for the acquisition of control by Canadian Pacific, through its indirect, wholly owned subsidiary Cygnus Merger Sub 2 Corporation, of Kansas City Southern, and through it, of KCSR and its railroad affiliates, and for the resulting common control by Canadian Pacific of its U.S. railroad subsidiaries, and KCSR and its railroad affiliates.

DATES: Written comments on the Board's proposed procedural schedule are due by November 12, 2021.

ADDRESSES: Any filing submitted in this proceeding should be filed with the Board via e-filing on the Board's website. In addition, one copy of each filing must be sent (and may be sent by email only if service by email is acceptable to the recipient) to each of the following: (1) Secretary of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) Attorney General of the United States, c/o Assistant Attorney General, Antitrust Division, Room 3109, Department of Justice, Washington, DC 20530; (3) CP's representative, David L. Meyer, Law Office of David L. Meyer, 1105 S Street NW, Washington, DC 20009; (4) KCS's representative, William A. Mullins, Baker & Miller PLLC, Suite 300, 2401 Pennsylvania Avenue NW, Washington, DC 20037; (5) any other person designated as a Party of Record on the service list; and (6) the administrative law judge assigned in this proceeding, the Hon. Thomas McCarthy, 1331 Pennsylvania Avenue NW, Washington, DC 20004–1710, and at *ctolbert@fmshrc.gov* and *zbyers@fmshrc.gov.*

FOR FURTHER INFORMATION CONTACT: Valerie Quinn at (202) 245–0283. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On March 22, 2021, concurrently filed with their original notice of intent to file an application, CP and KCS jointly filed a petition to establish a procedural schedule. Applicants' proposed procedural schedule provides for a 10-month period between the date an application is filed and the date on which the Board would issue its final decision on the merits. (Pet. 1.)[1] Applicants request that the Board adopt their proposed procedural schedule so that the ''substantial benefits'' of the proposed transaction would not be ''unnecessarily delayed,'' and assert that their proposal, which is based on the procedural schedule adopted in *Canadian National Railway—Control—Illinois Central Corp.,* Docket No. FD 33556, is appropriate, given the similarities between the two transactions.[2] (Pet. 1–2.)

Given the high level of interest in this proceeding, as well as the complexity and magnitude of issues that may potentially arise, the Board proposes modifications to the schedule proposed by Applicants to ensure sufficient time for the submission and review of evidence and arguments, as well as for the careful consideration of the merits of the proposed transaction. Specifically, for deadlines pertaining to responsive applications, the Board proposes to conform to the time frames set forth in 49 U.S.C. 11325 and 49 CFR 1180.4 (2000). The Board also proposes more time for the filing of a rebuttal in support of, and responses to comments on, the primary application, as well as more time for responses to any responsive applications. Additionally, the Board's proposed schedule provides that any necessary public hearing or oral argument would be held on a date to be determined later in the proceeding.

Therefore, the Board proposes the following procedural schedule:[3]

F—Primary application and any related application(s) filed.

F+30—Board notice of acceptance of primary application and any related application(s) to be published in the **Federal Register**.

F+45—Notices of intent to participate due.

F+60—Proposed Safety Integration Plan (SIP) due.[4]

[1] In Applicants' amended notice, they express their continued ''desire that the Board adopt a schedule for its review of the proposed transaction of ten months or less.'' (Amended Notice 3.)

[2] On April 1, 2021, The Freight Rail Customer Alliance, National Coal Transportation Alliance, and Private Railcar Food and Beverage Association, Inc. (collectively, Shipper Associations), submitted a letter asserting that the transaction in Docket No. FD 33556 does not serve as a good benchmark, given the larger size and value of the Applicants' proposed transaction. (Shipper Associations Comment 4.)

[3] ''F'' designates the filing date of the application, and ''F+n'' means ''n'' days following that date. Applicants filed their application on October 29, 2021.

[4] Preparation of a SIP is required under 49 CFR 1106.4.

F+75—Descriptions of anticipated responsive, including inconsistent, applications due. Petitions for waiver or clarification with respect to such applications due.

F+90—Comments (including from the U.S. Department of Justice (DOJ) and U.S. Department of Transportation (DOT), if any), protests, requests for conditions, and any other evidence and argument in opposition to the primary application or any related application(s) due.

F+115—Responsive environmental information and environmental verified statements for responsive, including inconsistent, applicants due.

F+120—Responsive, including inconsistent, applications due.

F+145—Responses to comments (including those of DOJ and DOT, if any), protests, requests for conditions, and other opposition due. Rebuttal in support of the primary application and any related application(s) due.

F+150—Notice of acceptance of responsive, including inconsistent, applications, if any, published in the **Federal Register**.

F+175—Responses to responsive, including inconsistent, applications due.

F+205—Rebuttals in support of responsive, including inconsistent, applications due.

F+245—Final briefs due.[5]

TBD—Public hearing (if necessary). (Close of the record.)[6]

TBD—Service date of final decision.[7]

The Board invites all interested persons to submit written comments on the procedural schedule proposed here. Comments must be filed by November 12, 2021. The dates proposed in this decision are subject to change depending on the comments received or other circumstances. The Board also notes that it may grant requests to extend the filing deadlines set in the procedural schedule for good cause. *See* 49 CFR 1104.7(b).

The Board's Office of Environmental Analysis will review the information that it has requested from Applicants needed to initiate the environmental review of the proposed transaction. The Board will address environmental review issues in a subsequent decision.

Decided: November 1, 2021.

By the Board, Board Members Begeman, Fuchs, Oberman, Primus, and Schultz.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2021–24307 Filed 11–5–21; 8:45 am]

BILLING CODE 4915–01–P

[5] The Board will also provide page limits for final briefs in a later decision after the record has been more fully developed.

[6] The Board will decide whether to conduct a public hearing in a later decision after the record has been more fully developed. *See* 49 U.S.C. 11324(a) (''The Board shall hold a public hearing unless the Board determines that a public hearing is not necessary in the public interest.'').

[7] Applicants' proposed schedule includes a date for the issuance of the Board's final decision. The Board will issue its final decision in accordance with 49 U.S.C. 11325(b)(3) (requiring a final decision to be issued within 90 days of the close of the evidentiary record).

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meetings

TIME AND DATE: 10 a.m. on November 10, 2021.

PLACE: Please use the following link for the live stream of meeting: *https://tva.com/board/watch.*

STATUS: Open, via live streaming only.

MATTERS TO BE CONSIDERED:

Meeting No. 21–04

The TVA Board of Directors will hold a public meeting on November 10, 2021. Due to the ongoing risks associated with the COVID–19 outbreak, the meeting will be streamed to the public. The meeting will be called to order at 10 a.m. ET to consider the agenda items listed below. TVA Board Chair Bill Kilbride and TVA management will answer questions from the news media following the Board meeting.

Public health concerns also require a change to the Board's public listening session. Although in-person comments from the public are not feasible, the Board is encouraging those wishing to express their opinions to submit written comments that will be provided to the Board members before the November 10 meeting. Written comments can be submitted through the same online system used to register to speak at previous listening sessions.

Agenda

1. Approval of minutes of the August 18, 2021 Board Meeting
2. Report of the Audit, Finance, Risk, and Cybersecurity Committee
   A. Fiscal Year 2023 Pandemic Recovery Credit
   B. Financial Hedging Program
3. Report of the Operations and Nuclear Oversight Committee
   A. Cumberland and Kingston—Plant Retirement and Generation Alternatives Delegation
4. Report of the External Stakeholders and Regulation Committee
   A. Recognition of Local Power Company
   B. TVA's Biodiversity Policy
5. Report of the People and Governance Committee
   A. Fiscal Year 2021 Performance and Compensation
   B. CEO Compensation for Fiscal Year 2022
6. Governance Item
   A. Assistant Corporate Secretary Designations
7. Information Item
   A. Committee Charters
   B. Arrangements with Direct-Service Customers
8. Report from President and CEO

CONTACT PERSON FOR MORE INFORMATION: For more information: Please call Jim Hopson, TVA Media Relations at (865) 632–6000, Knoxville, Tennessee. Anyone who wishes to comment on any of the agenda in writing may send their comments to: TVA Board of Directors, Board Agenda Comments, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Dated: November 3, 2021.

Edward C. Meade,

Agency Liaison.

[FR Doc. 2021–24467 Filed 11–4–21; 11:15 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Release of Land Affecting Federal Grant Assurance Obligations at Brown Field Municipal Airport, San Diego, San Diego County, California

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of request to release airport land.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal and invites public comment to change a portion of the airport from aeronautical use to non-aeronautical use at Brown Field Municipal Airport, San Diego, San Diego County, California. The proposal consists of 51 parcels containing approximately 197.96 acres of airport land, located on the airfield.

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

ADDRESSES: Comments on the request may be mailed or delivered to the FAA at the following address: Ms. Cathryn Cason, Manager, Los Angeles Airports District Office, Federal Aviation Administration, 777 South Aviation Boulevard, Suite 150, El Segundo, California 90245. In addition, one copy of the comment submitted to the FAA must be mailed or delivered to Mr. Jorge Rubio, A.A.E., C.A.E., Deputy Director, Airport Management, Department of Real Estate and Airport Management,

City of San Diego, 3750 John J. Montgomery Drive, San Diego, California 92123.

SUPPLEMENTARY INFORMATION: The land was originally acquired by the City through the Federal Property and Administrative Services Act of 1949 and the Surplus Property Act of 1944, via a quitclaim deed issued by the General Services Administration on September 1, 1962. The land will be leased for non-aeronautical revenue generation. Such use of the land represents a compatible land use that will not interfere with the airport or its operation, thereby protecting the interests of civil aviation. The airport will be compensated for the fair market value of the use of the land.

In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 106–181 (Apr. 5, 2000; 114 stat. 75), this notice must be published in the **Federal Register** 30 days before the DOT Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

Issued in El Segundo, California, on November 3, 2021.

Brian Q. Armstrong,

Manager, Safety and Standards Branch, Airports Division, Western-Pacific Region.

[FR Doc. 2021–24351 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent of Waiver with Respect to Land; Dayton-Wright Brothers Airport, Dayton, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is considering a proposal to change 5 acres of airport land from aeronautical use to non-aeronautical use and to authorize the lease of airport property located at Dayton-Wright Brother Airport, Dayton, OH. The aforementioned land is not needed for aeronautical use. The subject property is vacant land located on the southeast corner of North Springboro Pike and Austin Boulevard. The property is proposed to be leased to an existing airport tenant for the non-aeronautical expansion of an office complex.

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

ADDRESSES: Documents are available for review by appointment at the FAA Detroit Airports District Office, Alex Erskine, Program Manager, 11677 South Wayne Road, Suite 107, Romulus, MI 48174. Telephone: (734) 229–2927/Fax: (734) 229–2950 and City of Dayton Department of Aviation Offices, 3600 Terminal Drive, Suite 300, Vandalia OH, Mr. Gilbert Turner. Telephone: (937) 454–8202.

Written comments on the Sponsor's request must be delivered or mailed to: Alex Erskine, Program Manager, Federal Aviation Administration, Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, MI 48174, Telephone Number: (734) 229–2927/FAX Number: (734) 229–2950.

FOR FURTHER INFORMATION CONTACT: Alex Erskine, Program Manager, Federal Aviation Administration, Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, MI 48174. Telephone Number: (734) 229–2927/FAX Number: (734) 229–2950.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The property is currently vacant land that is located on airport Parcel 1. Parcel 1 is part of the original 344.85-acre airport site. The airport has received five Airport Development Aid Program (ADAP) grants and one Airport Improvement Program (AIP) grant (3–39–0030–001–1982) that each included partial land reimbursement for the original 344.85-acre airport site. The proposed land use of the 5-acre site is for the non-aeronautical expansion of an existing airport tenant's business operations. The tenant plans to immediately construct a two-story architecturally unique office building with approximately 40 parking spaces on the western most 1.146 acres of the 5-acre site. The tenant anticipates additional future non-aeronautical expansion on the remaining 3.854 acres at a later date that will be compatible with airport operations. The airport will receive Fair Market Value lease rates for this land lease.

The disposition of proceeds from the lease of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the Dayton-Wright Brothers Airport, Dayton, OH from its obligations to be maintained for aeronautical purposes. Approval does not constitute a commitment by the FAA to financially assist in the change in use of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

Lease Discription of 1.146 Acres

Situated in the State of Ohio, County of Montgomery, Township of Miami, Section 10, Township 2, Range 5 M.Rs., being 1.146 acres of that 57.72 acre tract described as Parcel II in a deed to the City of Dayton, Ohio, of record in Deed Microfiche 74–23D06, all references herein being to the records of the Recorder's Office, Montgomery County, Ohio, and being more particularly described as follows: Beginning FOR REFERENCE at a 1'' rebar found in a monument box at the centerline intersection of State Route 741 (Springboro Pike) and Austin Boulevard (County Road 166); thence South 88°30′19″ East, along the centerline of Austin Boulevard, a distance of 542.98 feet to a point; thence South 01°29′41″ West, a distance of 107.52 feet to a point in the southerly limited access right of way line of Austin Boulevard at the northeasterly corner of a 7.556 acre lease parcel described in a deed to The Conner Group, of record in Instrument No. 2020–00035418 and the TRUE PLACE OF BEGINNING;

Thence North 84°42′39″ East, along said southerly limited access right of way line, a distance of 127.83 feet to a point; Thence though said 57.72 acre tract the following courses: 1. South 01°29′39″ West, a distance of 360.42 feet to a point; 2. North 88°50′45″ West, a distance of 59.20 feet to a point of curvature; 3. With the arc of a curve to the left having a radius of 149.07 feet, a central angle of 39°05′21″, an arc length of 101.70 feet, the chord of which bears South 71°36′34″ West, a chord distance of 99.74 feet to a point in the easterly perimeter of said lease parcel (7.556 acres); Thence North 05°25′20″ East, along said easterly perimeter, a distance of 380.48 feet to the TRUE PLACE OF BEGINNING and containing 1.146 acres of land.

Lease Description of 3.854 Acres

Situated in the State of Ohio, County of Montgomery, Township of Miami, Section 10, Township 2, Range 5 M.Rs., being 3.854 acres of that 57.72 acre tract described as Parcel II in a deed to the City of Dayton, Ohio, of record In Deed Microfiche 74–23D06, all references herein being to the records of the Recorder's Office, Montgomery County, Ohio, and being more particularly described as follows:

Beginning FOR REFERENCE at a 1″ rebar found in a monument box at the centerline intersection of State Route 741 (Springboro Pike) and Austin Boulevard (County Road 166); thence South 88°30′19″ East, along the centerline of Austin Boulevard, a distance of 542.98 feet to a point; thence South 01°29′41″ West, a distance of 107.52 feet to a point in the southerly limited access right of way line of Austin Boulevard at the northeasterly corner of a 7.556 acre lease parcel described in a deed to The Conner Group, of record in Instrument No. 2020–00035418; thence North 84°42′39″ East, along said southerly right of way line, a distance of 127.83 feet to an iron pin found at a angle point in said right of way line and the TRUE PLACE OF BEGINNING;

Thence South 88°30′19″ East, continuing along said southerly limited access right of way line and the unrestricted access southerly right of way line of Austin Boulevard, a distance of 466.59 feet to a point; Thence though said 57.72 acre tract the following courses: (1) South 01°09′15″ West, a distance of 357.64 feet to a point; (2) North 88°50′45″ West, a distance of 468.72 feet to a point; 3. North 01°29′39″ East, a distance of 360.42 feet to the TRUE PLACE OF BEGINNING and containing 3.854 acres of land.

Issued in Romulus, Michigan, on November 2, 2021.

Stephanie Swann,

Acting Manager, Detroit Airports District Office, FAA, Great Lakes Region.

[FR Doc. 2021–24319 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0124]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption from ZF Group's Commercial Vehicle Control Systems Division

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; grant of exemption.

SUMMARY: The FMCSA announces its decision to grant the application of ZF Group's Commercial Vehicle Control Systems Division (ZF CVCS) for a limited five-year exemption to allow its advanced driver-assistance systems (ADAS) camera to be mounted lower in the windshield on commercial motor vehicles (CMV) than is currently permitted. The Agency has determined that lower placement of the ZF CVCS ADAS camera would not have an adverse impact on safety and that adherence to the terms and conditions of the exemption would likely achieve a level of safety equivalent to, or greater than, the level of safety provided by the regulation.

DATES: This exemption is effective November 8, 2021 and ending November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Mr. José R. Cestero, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–5541, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Docket: For access to the docket to read background documents or comments submitted to notice requesting public comments on the exemption application, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations. The online Federal document management system is available 24 hours a day, 365 days a year. The docket number is listed at the beginning of this notice.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the 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 any safety analyses that have been conducted. The Agency must also 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 achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

ZF CVCS's Application for Exemption

ZF CVCS applied for an exemption from 49 CFR 393.60(e)(1) to allow its ADAS camera to be mounted lower in the windshield than is currently permitted to optimize its functionality. A copy of the application is included in the docket referenced at the beginning of this notice.

In its application, ZF CVCS stated that the functionality of its camera includes the ability to provide Collision Mitigation Systems, Adaptative Cruise Control, Lane Departure Warning, Lane Keeping Assist, VRU Collision Mitigation, High Beam Assist, and Traffic Sign Recognition. ZF CVCS noted that it has virtually evaluated the impact of camera housings using digital human modeling software, and also installed a prototype camera housings in several commercial motor and found no noticeable obstruction to the normal sight lines to the road ahead, highway signs, signals, or any mirrors.

Currently, ZF CVCS offers two camera system models. The first model has a housing that is approximately 142 mm (5.6 inches) tall by 138 mm (5.4 inches) wide. The second model has a housing that is 110 mm (4.30 inches) tall by 118 mm (4.67 inches) wide. The selected camara system will be mounted in the approximate center of the windshield with the bottom edge of the technology housing approximately 204 mm (approximately 8 inches) below the upper edge of the area swept by the windshield wipers. The device will be mounted outside the driver's normal sight lines to the road ahead, signs, signals and mirrors. This location will allow for optimal functionality of the safety features supported by the camera.

Without the proposed exemption, ZF CVCS stated that its clients would not be able to install these devices in an optimal location to maximize their safety features. The exemption would apply to all CMVs equipped with ZF CVCS' ADAS camera mounted on the windshield. ZF CVCS believes that mounting the ADAS camera system as described will maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

Comments

FMCSA published a notice of the application in the **Federal Register** on August 12, 2021 and asked for public comment (86 FR 44467). The Agency received no comments.

FMCSA Decision

FMCSA has evaluated the ZF CVCS exemption application. The ADAS camera system housing for both models are approximately 4.30 and 5.6 inches tall and are mounted near the top of the center of the windshield, with the bottom of the technology housing located approximately 8 inches below the top of the area swept by the windshield wipers. The camera needs to be mounted in this location for optimal functionality of the ADAS system. The desired functionality and the relative size of the device precludes mounting it (1) higher in the windshield, and (2) within 4 inches from the top of the area swept by the windshield wipers to comply with section 393.60(e)(1)(ii)(A).

The Agency believes that allowing placement of the ADAS camera lower than currently permitted by Agency regulations will likely provide a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption because (1) based on the information available, there is no indication that the ADAS camera would obstruct drivers' views of the roadway, highway signs and signals, and surrounding traffic; (2) generally, trucks and buses have an elevated seating position that greatly improves the forward visual field of the driver and any impairment of available sight lines would be minimal; and (3) the mounting location where the bottom of the ADAS camera housing does not extend more than 8 inches below the upper edge of the area swept by the windshield wipers outside the driver's and passenger's normal sight lines to the road ahead, highway signs and signals, and all mirrors, will be reasonable and enforceable at roadside. In addition, the Agency believes the use of the ADAS camera by fleets is likely to improve the overall level of safety for the motoring public.

This action is consistent with the following previously issued Agency actions permitting the placement of similarly-sized devices on CMVs outside the driver's sight lines to the road and highway signs and signals: Bendix Commercial Vehicle Systems, LLC 86 FR 17877 (April 6, 2021), Netradyne, Inc. 85 FR 82575 (Dec 18, 2020), J.J. Keller & Associates, Inc. 85 FR 75106 (November 24, 2020), Samsara Networks, Inc. 85 FR 68409 (Oct. 28, 2020), Nauto Inc. 85 FR 64220 (Oct. 9, 2020), Lytx Inc. 85 FR 30121 (May 21, 2020), and Navistar Inc. 84 FR 64952 (Nov. 25, 2019). FMCSA is unaware of any evidence showing that installation of other vehicle safety technologies mounted on the interior of the windshield has resulted in any degradation in safety.

Terms and Conditions for the Exemption

The Agency hereby grants the exemption for a 5-year period, beginning November 8, 2021 and ending November 9, 2026. During the temporary exemption period, motor carriers are allowed to operate CMVs equipped with ZF CVCS' ADAS camera in the approximate center of the top of the windshield where the bottom edge of the technology housing is approximately 8 inches below the upper edge of the area swept by the windshield wipers, outside of the driver's and passenger's normal sight lines to the road ahead, highway signs and signals, and all mirrors. The exemption is valid for 5 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) Motor carriers and/or commercial motor vehicles fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Interested parties possessing information that would demonstrate that motor carriers operating CMVs equipped with ZF CVCS' ADAS camera are not achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b), will take immediate steps to revoke the exemption.

Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Meera Joshi,

Deputy Administrator.

[FR Doc. 2021–24364 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2021–0006–N–15]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) abstracted below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before January 7, 2022.

ADDRESSES: Written comments and recommendations for the proposed ICR should be submitted on regulations.gov to the docket, Docket No. FRA–2021–0006. All comments received will be posted without change to the docket, including any personal information provided. Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer, at email: *hodan.wells@dot.gov* or telephone: (202) 493–0440.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) Whether the

information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, FRA reasons that comments received will advance three objectives: (1) Reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Passenger Equipment Safety Standards.

OMB Control Number: 2130–0544.

Abstract: The information collection under 49 CFR part 238 is used by FRA to promote passenger train safety by ensuring requirements are met for railroad equipment design and performance, fire safety, emergency systems, inspection, testing, and maintenance, and other provisions for the safe operation of railroad passenger equipment. For instance, the information collected from daily inspections is used to detect and correct equipment problems in order to prevent, to the extent that they can be prevented, collisions, derailments, and other occurrences involving railroad passenger equipment that cause injury or death to railroad employees, railroad passengers, or to the general public.

Upon detailed review of part 238, FRA made several adjustments to its estimated paperwork burdens in this ICR extension.[1] As noted in the PRA table below, FRA determined that many estimated paperwork burdens were either outdated or accounted for in other regulatory sections. Additionally, FRA found the associated burdens related to train equipment inspection and testing, as well as employee training and job briefings have been addressed previously when FRA calculated the economic costs of the regulation. FRA also notes below where it anticipates zero railroad submissions during this 3-year ICR period.

Type of Request: Extension without change (with changes in estimates) of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 34 railroads and manufacturers.

Frequency of Submission: On occasion.

REPORTING BURDEN

CFR Section[2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent[3]
229.47(a)–(b)—Emergency Brake Valve—Marking brake pipe valve as such.	FRA anticipates zero submissions for stencils and markings.				
238.7—Waivers	34 railroads	12 waivers	6 hours	72.00	$5,575.68
238.15(b)—Movement of passenger equipment with power brake defects—Limitations on movement of passenger equipment containing a power brake defect at the time a Class I or IA brake test is performed—Passenger equipment tagged or information is recorded as prescribed under § 238.18(c)(2).	34 railroads	1,000 tags	3 minutes	50.00	3,872.00
—(c) Limitations on movement of passenger equipment in passenger service that becomes defective en route after a Class I or IA brake test—Tagging of defective equipment.	34 railroads	288 tags	3 minutes	14.40	1,115.14
—(c)(4) Conditional requirement—Notice between employees.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is covered under § 238.15(a)–(b).				
238.17—Movement of passenger equipment with other than power brake defects—Tagging of defective equipment.	34 railroads	200 tags	3 minutes	10.00	774.40
—(e) Special requisites for movement of passenger equipment with safety appliance defects.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is covered under § 238.17.				
—(e)(4) Crew member notifications	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is covered under § 238.17.				
238.19(b)–(c)—Reporting and tracking defective passenger equipment—Retention or availability of records.	FRA determined, since the 1990s, retention and availability of records for reporting and tracking defective passenger equipment are handled by the railroad industry as part of their normal business operations.				

[1] The public can view any and all estimate adjustments to FRA's active ICRs in the Supporting Statements published at *https://www.reginfo.gov/public/*. The Supporting Statement for this ICR will be available after the 30-Day **Federal Register** notice is published in *reginfo.gov*.

REPORTING BURDEN—Continued

CFR Section [2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [3]
—(d) List of power brake repair points	This ICR only affects Amtrak, which has submitted the necessary list of power brake repair points. FRA does not anticipate any changes or updates to this list over the next few years. Consequently, there is no burden associated with this requirement.				
238.21(b)—Special approval procedure—Petitions for special approval of alternative standard.	34 railroads	1 petition	16 hours	16.00	1,239.04
—(c) Petitions for special approval of alternative compliance.	34 railroads	1 petition	40 hours	40.00	3,097.60
—(f) Comments on petitions	Manufacturers and public	2 comments	1 hour	2.00	154.88
238.103(c)—Fire safety analysis for procuring new passenger cars and locomotives.	1 new railroad	1 analysis	150 hours	150.00	11,616.00
—(d) Fire safety analysis for existing passenger cars and locomotives—Revised Fire Safety Analysis for leased or transferred equipment.	34 railroads	1 revised analysis	10 hours	10.00	774.40
238.105—Train electronic hardware and software safety—New railroads.	1 new railroad	1 program plan	150 hours	150.00	11,616.00
238.107—Inspection, testing, and maintenance plan—Development of maintenance plan for new railroads.	1 new railroad	1 maintenance plan	150 hours	150.00	0.00
—(c) Inspection, testing, and maintenance plan for existing railroads—Maintenance plan review.	34 railroads	34 maintenance plan reviews.	20 hours	680.00	52,659.20
238.109(b)—Training, qualification, and designation program—Development of training program/curriculum for new railroads.	1 new railroad	1 training program	160 hours	160.00	0.00
—(b) Training employees and supervisors.	The associated burdens relating to the training of employees and supervisors have been addressed previously when FRA calculated the economic costs of the regulation.				
—(b)(13) Recordkeeping—Employees and trainers—Training qualifications.	34 railroads	488 records	3 minutes	24.40	1,889.54
238.111(a)—Pre-revenue service acceptance testing plan: Passenger equipment that has previously been used in service in the U.S..	34 railroads	1 plan	16 hours	16.00	1,239.04
—(b) Passenger equipment that has not been previously used in revenue service in the U.S.	34 railroads	1 plan	192 hours	192.00	14,868.48
—(b) Subsequent equipment orders	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is covered above under § 238.111(a) and (b).				
—(b)(4) Tier II & Tier III passenger equipment: Report of test results to FRA.	1 railroad	1 letter	4 hours	4.00	309.76
—(b)(7) and (c) Plan submitted to FRA for Tier II or Tier III equipment before being placed in service.	In the past 20 years, FRA only received 1 modification plan. Thus, FRA anticipates zero modified plans in the next three years.				
238.131—Exterior side door safety systems—New passenger cars/locomotives used in passenger service—Failure Modes, Effects, Criticality Analysis (FMECA).	1 new railroad	1 analysis	80 hours	80.00	6,195.20
238.133(a)—Exterior side door safety systems—Passenger cars and locomotives used in a passenger service—By-pass device verification—Functional test plans.	1 new railroad	1 plan	4 hours	4.00	309.76
—(b) Unsealed door by-pass device—Notification to railroad's designated authority by train crewmember of unsealed door by-pass device.	The associated burdens related to safety job briefings have been addressed previously when FRA calculated the economic costs of the regulation.				

REPORTING BURDEN—Continued

CFR Section [2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [3]
—(c) En route failure—Safety briefing by train crew when door by-pass device is activated.	34 railroads	100 topic-specific briefings and notifications.	2 minutes	3.33	257.88
—(c) Notification to designated RR authority by train crewmember that door by-pass device has been activated.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.133(c).				
—(c)(1) On-site qualified person (QP) description to a qualified maintenance person (QMP) off-site that equipment is safe to move for repairs.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.133(c).				
—(c)(2) QP/QMP notification to crewmember in charge that door by-pass has been activated and safety briefing by train crew.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.133(c).				
—(d) Records	34 railroads	100 records	2 minutes	3.33	257.88
—(d) Records of unintended opening of a powered exterior side door.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.133(d).				
—(g)(2) RR record of by-pass activations found unsealed.	Duplicate estimate removed. The burden for this requirement is already covered above under § 238.133(d).				
238.135(a)(1)—Operating practices for exterior side door safety systems—Daily job briefings.	The associated burdens related to daily job briefings have been addressed previously when FRA calculated the economic costs of the regulation.				
—(c) Railroads' request to FRA for special consideration to operate passenger trains with exterior side doors or trap doors, or both, open between stations.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.7 or § 238.21 for purposes of this analysis only.				
—(c)(4) Railroads' response to FRA request for additional information concerning special consideration request.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.7 or § 238.21 for purposes of this analysis only.				
—(d) Operating rules on how to safely override a door summary circuit or no-motion system, or both, in the event of an en route exterior side door failure or malfunction on a passenger train (Note: Includes burden under § 238.137).	1 new railroad	1 operating rule	8 hours	8.00	619.52
—(d) Railroads to provide a copy of written operating rules to train crew members and control center personnel.	Railroads were required to complete the requirements of this subsection by December 6, 2018, so the estimated burden is zero.				
—(e) Railroads' training of train crew members on requirements of this section.	The associated burdens relating to the training of train crew members have been addressed previously when FRA calculated the economic costs of the regulation. FRA estimates the paperwork burdens associated with training recordkeeping under § 238.109 or under the OMB control numbers 2130–0596 or 2130–0533.				
—(e) Railroads' training of new employees.	The associated burdens relating to the training of new employees have been addressed previously when FRA calculated the economic costs of the regulation. FRA estimates the burdens associated with training recordkeeping under § 238.109 or under the OMB control numbers 2130–0596 or 2130–0533.				
—(g) RR operational/efficiency tests of train crew members & control center employees.	The associated burdens relating to operational testing or observation of operating crewmembers and control center personnel have been previously addressed when FRA calculated the economic costs of the regulation.				

REPORTING BURDEN—Continued

CFR Section [2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [3]
238.201(b)—Scope/alternative compliance—Supporting documentation demonstrating compliance.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.21.				
—(b) Notice of tests sent to FRA 30 days prior to commencement of operations.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.111(b)(4).				
238.229(c)—Safety appliances—Welded safety appliances—Written lists submitted to FRA by the railroads.	1 new railroad	1 list	1 hour	1.00	77.44
—(d) Defective welded safety appliance or welded safety appliance bracket or support—Tagging.	34 railroads	4 tags	3 minutes	.20	11.98
—(d) Notification to crewmembers about non-compliant equipment.	34 railroads	2 notices	1 minute	.03	2.32
—(g) Inspection plans	1 new railroad	1 plan	16 hours	16.00	1,239.04
—(h) Inspection personnel—Training	The associated burdens relating to training of inspection personnel have been addressed previously when FRA calculated the economic costs of the regulation. FRA estimates the paperwork burdens associated with the retention of training records under § 238.109.				
—(j)(1)(iv) Remedial action: Defect/crack in weld—A record of the welded repair.	The associated burdens relating to inspections have been addressed previously when FRA calculated the economic costs of the regulation. FRA estimates the paperwork burdens associated with the retention of inspection records under § 238.229(k).				
—(j)(2)(iv) Petitions for special approval of alternative compliance—Impractical equipment design.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.21.				
—(k) Records of the inspection and repair of the welded safety appliance brackets.	Duplicate estimate removed. The estimated burden for this regulatory requirement is already covered below under § 238.303 and under the OMB control number 2130–0004 (§ 229.21).				
238.230(b)(1)—Safety Appliances—New equipment—Inspection record of welded equipment by qualified employee.	FRA anticipates zero records.				
—(b)(3) Welded safety appliances: Documentation for equipment impractically designed to mechanically fasten safety appliance support.	FRA anticipates zero plans.				
238.231—Brake System—Inspection and repair of hand/parking brake: Records (under FRA Form 6180.49A).	The paperwork burden for this requirement is covered under § 238.303 and under the OMB control number 2130–0004.				
—(h) Procedures verifying hold of hand/parking brakes.	1 new railroad	1 procedure	2 hours	2.00	154.88
238.237(a)–(b)—Automated monitoring-Documentation for alerter/deadman control timing.	1 new railroad	1 document	2 hours	2.00	154.88
—(d) Defective alerter/deadman control: Tagging.	34 railroads	25 tags	3 minutes	1.25	74.86
238.303—Exterior calendar day mechanical inspection of passenger equipment: Notice of previous inspection.	FRA anticipates zero notices.				
—(e)(15) Dynamic brakes not in operating mode: Tag.	34 railroads	50 tags	3 minutes	2.50	149.73
—(e)(15)(ii) Conventional locomotives equipped with inoperative dynamic brakes: Tagging.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.303(e)(15).				

REPORTING BURDEN—Continued

CFR Section [2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [3]
—(e)(17) MU passenger equipment found with inoperative/ineffective air compressors at exterior calendar day inspection: Documents.	FRA anticipates zero submissions.				
—(e)(17)(v) Written notice to train crew about inoperative/ineffective air compressors.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered above under § 238.303(e)(15).				
—(e)(18)(iv) Records of inoperative air compressors.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is already covered below under § 238.303(g).				
—(g) Record of exterior calendar day mechanical inspection (Other than locomotives) (*Note: Includes burden for records of inoperative air compressors under § 238.303(e)(18)(iv)).	34 railroads	1,734,115 daily inspection records.	1 minute	28,901.92	2,238,164.68
238.305—Interior calendar day mechanical inspection of passenger cars—Tagging of defective end/side doors.	34 railroads	540 tags	3 minutes	27.00	2,090.88
—(f) Records of interior calendar day inspection.	34 railroads	3,102,865 daily inspection records.	1 minute	51,714.42	4,004,764.68
238.307(a)(2)—Periodic mechanical inspection of passenger cars and unpowered vehicles—Alternative inspection intervals: Notifications.	34 railroads	2 notices	5 hours	10.00	774.40
—(c)(1) Notice of seats and seat attachments broken or loose.	34 railroads	200 notices	2 minutes	6.67	399.47
—(e)(1) Records of each periodic mechanical inspection.	34 railroads	5,184 inspection records.	1 hour	5,184.00	310,469.76
—(e)(2) Detailed documentation of reliability assessments as basis for alternative inspection interval.	34 railroads	2 documents	100 hours	200.00	15,488.00
238.311—Single car test—Tagging to indicate need for single car test.	34 railroads	50 tags	3 minutes	2.50	149.73
238.313(h)—Class I Brake Test—Record for additional inspection for passenger equipment that does not comply with § 238.231(b)(1).	34 railroads	15,600 records	30 minutes	7,800.00	467,142.00
238.315(a)(1)—Class IA brake test—Notice to train crew that test has been performed (verbal notice).	The associated burdens related to briefings have been addressed previously when FRA calculated the economic costs of the regulation.				
—(f)(5) Communicating signal tested and operating as intended.	The associated burdens related to briefings have been addressed previously when FRA calculated the economic costs of the regulation.				
238.317—Class II brake test—Communicating signal tested and operating as intended.	The associated burdens related to briefings have been addressed previously when FRA calculated the economic costs of the regulation.				
238.321—Out-of-service credit—Passenger car: Out-of-use notation.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is covered under § 238.307 and under OMB control number 2130–0004 under 229.23(d)–(g).				
238.445(a)—Automated Monitoring—Performance monitoring: alerters/alarms.	There are no paperwork burdens associated with this subsection. FRA corrects its previous over-inclusion.				
—(c) Monitoring system: Self-test feature: Notifications.	There are no paperwork burdens associated with this subsection. FRA corrects its previous over-inclusion.				
238.703—Quasi-static compression load requirements—Document to FRA on Tier III trainsets.	1 new railroad	.33 document	40 hours	13.20	1,022.21
238.705—Dynamic collision scenario—Model validation document to FRA for review and approval.	1 new railroad	.33 validation document.	40 hours	13.20	1,022.21
238.707—Override protection—Anti-climbing performance evaluation for Tier III trainsets.	1 new railroad	.33 evaluation	40 hours	13.20	1,022.21

REPORTING BURDEN—Continued

CFR Section [2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [3]
238.709—Fluid entry inhibition—Information to demonstrate compliance with this section of a Tier III trainset.	1 new railroad	.33 analysis	20 hours	6.60	511.10
238.721—Glazing—Cab glazing; end facing—Documentation containing technical justification.	3 glass manufacturers.	.33 technical documentation.	60 hours	19.80	1,533.31
—(a)(6) Marking of end-facing exterior windows for Tier III trainsets.	Windows are, customarily, automatically marked during the production process. Therefore, there will be no additional burden to mark the windows.				
—(b) Cab Glazing; side-facing exterior windows in Tier III cab—Each end-facing exterior window in a cab shall, at a minimum, provide ballistic penetration resistance that meets the requirements of appendix A to part 223 (Certification of Glazing Materials).	3 glass manufacturers.	.33 analysis	10 hours	3.30	255.55
—(b) Marking of side-facing exterior windows in Tier III Trainsets.	Windows are, customarily, automatically marked during the production process. Therefore, there will be no additional burden to mark the windows.				
—(c) Non-Cab Glazing; Side-facing exterior windows—Tier III—compliance document for Type II glazing.	3 glass manufacturers.	.33 analysis	20 hours	6.60	511.10
—(c) Marking of side-facing exterior windows—Tier III Trainsets—non-cab cars.	Windows are, customarily, automatically marked during the production process. Therefore, there will be no additional burden to mark the windows.				
—(c)(2) Alternative standard to FRA for side-facing exterior window intended to be breakable and serve as an emergency window exit (option to comply with an alternative standard).	3 glass manufacturers.	.67 alternative analysis.	5 hours	3.35	259.42
238.731(a)—Brake Systems—RR analysis and testing Tier III trainsets' maximum safe operating speed.	Duplicate estimate removed. The estimated paperwork burden for this regulatory requirement is covered under § 238.111(b).				
—(d) Tier III trainsets' passenger brake alarm—legible stenciling/marking of devices with words ''Passenger Brake Alarm'' (Including the design of the sticker).	1 new railroad	53.33 stencilings	1 hour (design) + 2 minutes (marking).	55.11	3,300.54
—(f) Main reservoir test/certification	1 new railroad	.33 certification	6 hours	1.98	118.58
—(h) Main reservoir tests—Inspection, testing and maintenance (ITM) plan.	1 railroad	.33 ITM plan	10 hours	3.30	255.55
—(j) Brake application/release—Brake actuator design with approved brake cylinder pressure as part of design review process.	1 railroad	.33 design	40 hours	13.20	1,022.21
—(o) Train securement—Tier III equipment: demonstrated securement procedure.	1 railroad	.33 procedure	8 hours	2.64	204.44
238.733—Interior fixture attachment—Analysis for FRA approval (Tier III).	1 railroad	.33 analysis/document.	20 hours	6.60	511.10
238.735—Seat crashworthiness standard (passenger & cab crew)—Analysis for FRA approval (Tier III).	1 railroad	.33 analysis/document.	40 hours	13.20	1,022.21
238.737—Luggage racks—Analysis for FRA approval (Tier III).	1 railroad	.33 analysis/document.	20 hours	6.60	511.10
238.741—Emergency window egress and rescue access—Plan to FRA for passenger cars in Tier III trainsets not in compliance with sections 238.113 or 238.114.	1 railroad	.33 plan	60 hours	19.80	1,533.31
238.743—Emergency Lighting—Analysis for FRA approval (Tier III).	1 railroad	.33 analysis/test	60 hours	19.80	1,533.31

REPORTING BURDEN—Continued

CFR Section [2]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [3]
238.751—Alerters—Alternate technology—Analysis for FRA approval (Tier III).	1 railroad	.33 analysis/test	40 hours	13.20	1,022.21
Total	34 railroads	4,860,940 Responses.	N/A	95,946	7,149,477

Total Estimated Annual Responses: 4,860,940.

Total Estimated Annual Burden: 95,946 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $7,149,477.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2021–24300 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–06–P

[2] The current inventory exhibits a total burden of 4,600,273 hours while the total burden of this notice is 95,946 hours. As part of its review of this ICR renewal, FRA determined some of the previous estimates were initial estimates, outdated, duplicative, or outside the scope of the PRA. For instance, the burdens previously associated with 49 CFR 238.303(g), 238.305(f), and 238.307(e) were significantly adjusted after removing the inspection times from the burden hours. This adjustment is correct because the burden is imposed by the underlying regulation, thus times for the inspection did not arise from this information collection requirement, so it was incorrect to quantify them as costs related to the information collection.

[3] The dollar equivalent cost is derived from the Surface Transportation Board's 2020 Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes a 75-percent overhead charge.

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0011]

Deepwater Port License Application: SPOT Terminal Services LLC; Correction

AGENCY: Maritime Administration, Department of Transportation, U.S. Coast Guard, Department of Homeland Security.

ACTION: Correcting amendment; notice of availability; notice of public meeting and request for comments.

SUMMARY: On October 29, 2021, the Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announced the availability of the Supplemental Draft Environmental Impact Statement (SDEIS) for the SPOT Terminal Services LLC (SPOT) Deepwater port license application for the export of oil from the United States to nations abroad, announced a virtual public meeting for the SDEIS, and the October 29 notice began a 45-day comment period seeking public participation in the environmental impact review process, provided information on how to participate in the environmental impact review process, directed interested parties to a Notice of Application that summarized the SPOT Deepwater Port License Application published in the **Federal Register** on March 4, 2019, a Notice of Intent to Prepare an Environmental Impact Statement (EIS) and Notice of Public Meetings that were published in the **Federal Register** on March 7, 2019. This notice restates the same information and serves only to correct the email address *Efrain.Lopez@dot.gov* in the **FOR FURTHER INFORMATION CONTACT** section.

DATES: The public meeting will be held virtually, on November 16, 2021, from 6:00 p.m. to 8:00 p.m. Central Standard Time (CST).

Additionally, materials submitted in response to this request for comments on the SDEIS must be submitted to the *www.regulations.gov* website or the Federal Docket Management Facility as detailed in the **ADDRESSES** section below no later than 45 days after the Environmental Protection Agency (EPA) publishes its notice of availability of the SDEIS for the SPOT Deepwater Port License Application in the **Federal Register**.

ADDRESSES: The public docket for the SPOT Deepwater Port License Application is maintained by the U.S. Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. Comments on the SDEIS may be submitted to this address and must include the docket number for this project, which is MARAD–2019–0011. The Federal Docket Management Facility's telephone number is 202–366–9317 or 202–366–9826, the fax number is 202–493–2251.

We encourage you to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* If you submit your comments electronically, it is not necessary to also submit a hard copy by mail. If you cannot submit material using *http://www.regulations.gov,* please contact either Mr. Matthew Layman, USCG, or Dr. Efrain Lopez, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Layman, U.S. Coast Guard, telephone: 202–372–1421, email: *Matthew.D.Layman@uscg.mil,* or Dr. Efrain Lopez, Maritime Administration, telephone: 202–366–9761, email: *Efrain.Lopez@dot.gov.* For questions regarding viewing the Docket, call Docket Operations, telephone: 202–366–9317 or 202–366–9826.

SUPPLEMENTARY INFORMATION: MARAD and USCG will hold one virtual public meeting in connection with the SPOT SDEIS. The virtual public meeting will be held remotely due to the nationwide impacts of the existing public health emergency under Section 319 of the Public Health Service Act in response to Coronavirus Disease 2019 (COVID–19). Further, the President's declaration of a national emergency due to the COVID–19 outbreak, and state and local actions in response to COVID–19, have impacted the public's ability to assemble and provide feedback on the SPOT deepwater port license application through in-person public meetings. The public meeting will be held virtually, on November 16, 2021, from 6:00 p.m. to 8:00 p.m. Central Standard Time (CST). The public meeting may end later than the stated time, depending on the number of persons who wish to make a comment on the record. Anyone that is interested in attending the virtual public meeting or speaking during the virtual public meeting must register. Registration information is provided in the Virtual Public Meeting and Registration sections of this Notice. Additionally, materials submitted in response to this request for comments on the SDEIS

must be submitted to the *www.regulations.gov* website or the Federal Docket Management Facility as detailed in the **ADDRESSES** section below no later than 45 days after the Environmental Protection Agency (EPA) publishes its notice of availability of the SDEIS for the SPOT Deepwater Port License Application in the **Federal Register**. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

Virtual Public Meeting

The public meeting will be held virtually, on November 16, 2021, from 6:00 p.m. to 8:00 p.m. Central Standard Time (CST). The virtual platform of choice is Zoom. We encourage you to visit the informational virtual open house website (*www.SPOTNEPAProcess.com*) and to attend the virtual public meeting to learn about, and comment on, the proposed SPOT deepwater port. You will have the opportunity to verbally submit comments during the virtual public meeting on the scope and significance of the issues related to the proposed deepwater port that should be addressed in the SDEIS.

Registration

Speaker and attendee registration are available online at *www.SPOTNEPAProcess.com.* Speakers at the virtual public meeting will be recognized in the following order: Elected officials, public agencies, individuals, or groups in the sign-up order and then anyone else who wishes to speak. In order to allow everyone a chance to speak at a virtual public meeting, we may limit speaker time, extend the meeting hours, or both. You must identify yourself and any organization you represent by name. Speakers' transcribed remarks will be included in the public docket. You may also submit written material for inclusion in the public docket. Written material must include the author's name. We ask attendees to respect the meeting procedures in order to ensure a constructive information-gathering session. The presiding officer will use his/her discretion to conduct the meeting in an orderly manner.

Public meetings are intended to be accessible to all participants. Individuals who require special assistance such as sign language interpretation, non-English language translation services or other reasonable accommodations, please notify the USCG or MARAD (see **FOR FURTHER INFORMATION CONTACT**) at least 7 business days in advance of the virtual public meeting. Include your contact information as well as information about your specific needs.

Request for Comments

We request public comment on this SDEIS. All comments will be accepted. The virtual public meeting is not the only opportunity you have to comment on the SPOT deepwater port license application. In addition to, or in place of, attending a virtual meeting, you may submit comments directly to the Federal Docket Management Facility during the public comment period (see **DATES**). We will consider all comments and material received during the 45-day public comment period.

Public comment submissions should include:

- Docket number MARAD–2019–0011.
- Your name and address.

Submit comments or material using only one of the following methods:

- Electronically (preferred for processing) to the Federal Docket Management System (FDMS) website: *http://www.regulations.gov* under docket number MARAD–2019–0011.
- By mail to the Federal Docket Management Facility (MARAD–2019–0011), U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- By fax to the Federal Docket Management Facility at 202–493–2251.

Faxed, mailed or hand delivered submissions must be unbound, no larger than 8½ by 11 inches and suitable for copying and electronic scanning. The format of electronic submissions should also be no larger than 8½ by 11 inches. If you mail your submission and want to know when it reaches the Federal Docket Management Facility, please include a stamped, self-addressed postcard or envelope.

Regardless of the method used for submitting comments, all submissions will be posted, without change, to the Federal Docket Management Facility website (*http://www.regulations.gov*) and will include any personal information you provide. Therefore, submitting this information to the docket makes it public. You may wish to read the Privacy and Use Notice that is available on the Federal Docket Management Facility website and the Department of Transportation Privacy Act Notice that appeared in the **Federal Register** on April 11, 2000 (65 FR 19477), see Privacy Act. You may view docket submissions at the Federal Docket Management Facility or electronically on the Federal Docket Management Facility website.

Background

On January 31, 2019, MARAD and USCG received a license application from SPOT for all Federal authorizations required for a license to construct, own, and operate a deepwater port for the export of oil. The proposed deepwater port would be located in Federal waters approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas. Texas was designated as the Adjacent Coastal State for the SPOT license application.

The Federal agencies involved held a public scoping meeting in connection with the evaluation of the SPOT license application. The public scoping meeting was held in Lake Jackson, Texas on March 20, 2019. The transcript of the scoping meeting is included on the public docket located at *https://www.regulations.gov/document/MARAD-2019-0011-0019.* The Federal agencies also held a Draft EIS public comment meeting to receive comments on the Draft EIS. The public comment meeting was held in Lake Jackson, Texas on February 26, 2020. Publication of that notice began a 45-day public comment period, which began on February 7, 2020 and ended on March 23, 2020. A second 30-day public comment period due to COVID began on May 1, 2021 and ended on May 31, 2021. The transcripts of the DEIS public comment meetings are also included on the public docket at *https://www.regulations.gov/document/MARAD-2019-0011-0019-1192.*

The purpose of the SDEIS is to provide language translation for Limited English Proficiency (LEP) persons in the Project vicinity. This action serves as required public engagement with Environmental Justice (EJ) communities and LEP persons. The SDEIS is currently available for public review at the Federal docket website: *www.regulations.gov* under docket number MARAD–2019–0011.

Summary of the License Application

SPOT is proposing to construct, own, and operate a deepwater port terminal in the Gulf of Mexico to export domestically produced crude oil. Use of the deepwater port would include the loading of various grades of crude oil at flow rates of up to 85,000 barrels per hour (bph). The SPOT deepwater port would allow for up to two (2) Very Large Crude Carriers (VLCCs) or other crude oil carriers to moor at single point mooring (SPM) buoys and connect with the deepwater port via floating connecting crude oil hoses and a

floating vapor recovery hose. The maximum frequency of loading VLCCs or other crude oil carriers would be 2 million barrels per day, 365 days per year.

The proposed SPOT Deepwater Port (DWP) would be located in Federal waters of the Gulf of Mexico, in Galveston Area Outer Continental Shelf lease blocks 463 and A–59, approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas, in water depths of approximately 115 feet. Onshore components of the proposed Project would be located in both Brazoria and Harris counties.

The overall project would consist of both onshore and offshore components. The onshore components would consist of:

- Modifications to the existing Enterprise Crude Houston (ECHO) Terminal, including four electric motor-driven mainline crude oil pumps, four electric motor-driven booster crude oil pumps, and one measurement skid to support delivery of crude oil to the proposed Oyster Creek Terminal;
- One 50.1-mile, 36-inch-diameter ECHO to Oyster Creek Pipeline;
- One pipeline interconnection from the existing Rancho II 36-inch-diameter pipeline to the ECHO to Oyster Creek Pipeline (Rancho II Junction);
- A new Oyster Creek Terminal on approximately 140 acres of land, including six electric motor-driven mainline crude oil pumps with the capacity to push crude oil to the offshore pipelines at a rate of up to 85,000 bph, four electric motor-driven booster crude oil pumps, seven aboveground storage tanks (each with a capacity of 685,000 barrels [600,000 barrels of working storage]) for a total onshore storage capacity of approximately 4.8 million barrels (4.2 million barrels working storage) of crude oil, metering equipment, two permanent and one portable vapor combustion units, and a firewater system;
- Two collocated 12.2-mile, 36-inch-diameter Oyster Creek to Shore Pipelines; and
- Ancillary facilities for the onshore pipelines, including ten mainline valves, of which six would be along the ECHO to Oyster Creek Pipeline and four along the Oyster Creek to Shore Pipelines, pig launchers for the ECHO to Oyster Creek Pipeline, and pig launchers and receivers for the Oyster Creek to Shore Pipelines.

The offshore and marine components would consist of:

- Two collocated, bi-directional, 46.9-mile, 36-inch-diameter crude oil offshore pipelines for crude oil delivery from the Oyster Creek Terminal to the platform;
- One fixed offshore platform with eight piles, four decks, and three vapor combustion units;
- Two SPM buoys to concurrently moor two VLCCs or other crude oil carriers with capacities between 120,000 and 320,000 deadweight tonnage for loading up to 365 days per year, including floating crude oil and vapor recovery hoses;
- Four pipeline end manifolds (PLEMs)—two per SPM buoy—to provide the interconnection between the SPOT DWP and the SPM buoys;
- Four 0.66-nautical mile, 30-inch-diameter pipelines (two per PLEM) to deliver crude oil from the platform to the PLEMs;
- Four 0.66-nautical mile, 16-inch diameter vapor recovery pipelines (two per PLEM) to connect the VLCC or other crude oil carrier to the three vapor combustion units on the platform.
- Three service vessel moorings, located in the southwest corner of Galveston Area lease block 463; and
- An anchorage area in Galveston Area lease block A–59, which would not contain any infrastructure.

The SDEIS that was prepared to ensure meaningful engagement of identified LEP persons in the environmental impact review process.

Privacy Act

Regardless of the method used for submitting comments or materials, all submissions will be posted, without change, to the *http://www.regulations.gov* website and will include any personal information you provide. Therefore, submitting this information to the docket makes it public. You may wish to read the Privacy and Security Notice and the User Notice that are available at *https://www.federalregister.gov/documents/2005/03/24/05-5823/establishment-of-a-new-system-of-records-notice-for-the-federal-docket-management-system.* The Privacy Act notice regarding the Federal Docket Management System is available in the March 24, 2005 issue of the **Federal Register** (70 FR 15086).

(Authority: 33 U.S.C. 1501 *et seq.,* 49 CFR 1.93(h)).

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24366 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Allocation Availability (NOAA) Inviting Applications for the Calendar Year (CY) 2021 Allocation Round of the New Markets Tax Credit (NMTC) Program

Funding Opportunity Title: Notice of Allocation Availability (NOAA) Inviting Applications for the Calendar Year (CY) 2021 Allocation Round of the New Markets Tax Credit (NMTC) Program.

Announcement Type: Announcement of NMTC Allocation availability.

Dates:

TABLE 1—CY 2021 ALLOCATION ROUND NMTC PROGRAM CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline/date	Time (eastern time—ET)	Submission method
Community Development Entity (CDE) Certification Application	November 18, 2021	11:59 p.m. ET	Electronically via the Awards Management Information System (AMIS).
Request to modify CDE certification service area	November 18, 2021	11:59 p.m. ET	Electronically via AMIS.
Subsidiary CDE Certification Application for meeting Qualified Equity Investment (QEI) issuance thresholds.	November 18, 2021	11:59 p.m. ET	Electronically via AMIS.
CY 2021 Application Registration	December 6, 2021	5:00 p.m. ET	Electronically via AMIS.
Last date to contact CDFI Fund staff	January 11, 2022	5:00 p.m. ET	Electronically via AMIS.
CY 2021 Allocation Application (including required Attachments)	January 13, 2022	5:00 p.m. ET	Electronically via AMIS.
Amendment request to add Subsidiary CDEs to Allocation Agreements for meeting QEI issuance thresholds.	January 20, 2022	11:59 p.m. ET	Electronically via AMIS.
QEI Issuance and making Qualified Low Income Community Investments (QLICIs) by.	March 21, 2022	11:59 p.m. ET	Not Applicable.
Amendment request to remove a Controlling Entity from Allocation Agreement(s).	March 21, 2021	11:59 p.m. ET	Electronically via AMIS.

TABLE 1—CY 2021 ALLOCATION ROUND NMTC PROGRAM CRITICAL DEADLINES FOR APPLICANTS—Continued

Description	Deadline/date	Time (eastern time—ET)	Submission method
Report QEIs and QLICIs by	March 28, 2022	11:59 p.m. ET	Electronically via AMIS.

Executive Summary: This NOAA is issued in connection with the CY 2021 allocation round (Allocation Round) of the New Markets Tax Credit Program (NMTC Program), as authorized by Title I, subtitle C, section 121 of the Community Renewal Tax Relief Act of 2000 (Pub. L. 106–554) as amended. Through the NMTC Program, the Community Development Financial Institutions Fund (CDFI Fund) provides authority to certified CDEs to offer an incentive to investors in the form of tax credits over seven years, which is expected to stimulate the provision of private investment capital that, in turn, will facilitate economic and community development in Low-Income Communities. Through this NOAA, the CDFI Fund announces the availability of $5 billion of NMTC Allocation authority in this Allocation Round.

In this NOAA, the CDFI Fund specifically addresses how a CDE may apply to receive an allocation of NMTCs, the competitive procedure through which NMTC Allocations will be made, and the actions that will be taken to ensure that proper allocations are made to appropriate entities.

I. Allocation Availability Description

A. Programmatic changes from the CY 2020 allocation round:

1. Prior QEI Issuance Requirements: Prior-year NMTC Allocatees will be subject to minimum thresholds for QEI issuance and closing of QLICIs with respect to their prior-year NMTC Allocations. These thresholds and deadlines have been revised in comparison to the CY 2020 NOAA. See Section III. A.5(a) of this NOAA for additional details.

2. Controlling Entity: The definition of Controlling Entity has been revised beginning with CY 2021 for Applicants that have not received allocations under prior NMTC Program rounds CY 2013 to CY 2020. Applicants will be required to meet the Controlling Entity definition in the CY 2021 Allocation Application. If awarded, a CY 2021 Applicant that has not received an allocation(s) under NMTC Program rounds CY 2013 to CY 2020 and designates a Controlling Entity, will be required to demonstrate that it meets the Controlling Entity definition in the CY 2021 Allocation Application no later than 60 days from the date it receives notification from the CDFI Fund of its allocation award. Applicants that received an allocation(s) under NMTC Program rounds CY 2013 to CY2020 that want to remove their Controlling Entity are required to submit the amendment request by the deadline in Table 1.

II. Allocation Information

A. Allocation amounts: Pursuant to the Taxpayer Certainty and Disaster Tax Relief Act of 2020, the CDFI Fund expects that it may allocate to CDEs the authority to issue to their investors the aggregate amount of $5 billion in equity as to which NMTCs may be claimed, as permitted under IRC § 45D(f)(1)(D). Pursuant to this NOAA, the CDFI Fund anticipates that it may issue up to $100 million in tax credit investment authority per Allocatee. The CDFI Fund, in its sole discretion, reserves the right to allocate amounts in excess of or less than the anticipated maximum allocation amount should the CDFI Fund deem it appropriate. The CDFI Fund reserves the right to allocate NMTC authority to any, all, or none of the entities that submit applications in response to this NOAA, and in any amounts it deems appropriate.

B. Type of award: NMTC Program awards are made in the form of allocations of tax credit investment authority.

C. Program guidance and regulations: This NOAA describes application and NMTC Allocation requirements for this Allocation Round of the NMTC Program and should be read in conjunction with: (i) The final NMTC Program Income Tax Regulations issued by the Internal Revenue Service (IRS) (26 CFR 1.45D–1, published on December 28, 2004), as amended and related guidance, notices and other publications; and (ii) the application and related materials for this Allocation Round. All such materials may be found on the CDFI Fund's website at *https://www.cdfifund.gov.* The CDFI Fund requires Applicants to review these documents. Capitalized terms used, but not defined, in this NOAA have the respective meanings assigned to them in the NMTC Program Allocation Application, Internal Revenue Code (IRC) § 45D or the IRS NMTC regulations. In the event of any inconsistency between this NOAA, the Allocation Application, and guidance issued by the CDFI Fund thereto, IRC § 45D or the IRS NMTC Regulations, the provisions of IRC § 45D and the IRS NMTC Regulations shall govern.

D. Allocation Agreement: Each Allocatee must sign an Allocation Agreement, which must be countersigned by the CDFI Fund, before the NMTC Allocation is effective. The Allocation Agreement contains the terms and conditions of the NMTC Allocation. For further information, see Section VI.B of this NOAA.

E. Statutory and national policy requirements: The CDFI Fund will manage and administer the NMTC Program in a manner so as to ensure that NMTC Allocations associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, statutory, and public policy requirements: including, but not limited to, those protecting free speech; religious liberty; public welfare; the environment; and prohibiting discrimination.

III. Eligibility

A. Eligible Applicants: IRC § 45D specifies certain eligibility requirements that each Applicant must meet to be eligible to apply for an allocation of NMTCs. The following sets forth additional detail and certain additional dates that relate to the submission of applications under this NOAA for the available NMTC Allocation authority.

1. CDE certification: For purposes of this NOAA, the CDFI Fund will not consider an application for an allocation of NMTCs unless: (a) The Applicant is certified as a CDE at the time the CDFI Fund receives its NMTC Program Allocation Application; or (b) the Applicant submits an application for certification as a CDE through AMIS by the deadline in Table 1. Applicants for CDE certification may obtain information regarding CDE certification and the CDE Certification Application process in AMIS on the CDFI Fund's website at *https://www.cdfifund.gov/programs-training/certification/cde/Pages/default.aspx.*

The CDFI Fund will not provide NMTC Allocation authority to Applicants that are not certified as CDEs or to entities that are certified as Subsidiary CDEs.

If an Applicant that has already been certified as a CDE wishes to change its designated CDE Service Area for this

Allocation Round, then it must submit its request for such change to the CDFI Fund, and the request must be received by the CDFI Fund by the deadline listed in

Table 1. A request to change a CDE's Service Area will need to include the revised service area designation and updated accountability information that demonstrates that the CDE has the required representation from Low-Income Communities in the revised CDE Service Area.

2. Repayment or Refinancing of QEI with QLICI Proceeds: An applicant must commit that it will not permit the use of the proceeds of QEIs to make QLICIs in Qualified Active Low-Income Community Businesses (QALICBs) where QLICI proceeds are used, in whole or in part, to repay or refinance a debt or equity provider whose capital was used to fund the QEI, or are used to repay or refinance any Affiliate of such a debt or equity provider, except where: (i) the QLICI proceeds are used to repay or refinance documented reasonable expenditures that are directly attributable to the qualified business of the QALICB, and such reasonable expenditures were incurred no more than 24 months prior to the QLICI closing date; or (ii) no more than five percent of the total QLICI proceeds from the QEI are used to repay or refinance documented reasonable expenditures that are directly attributable to the qualified business of the QALICB. Refinance includes transferring cash or property, directly or indirectly, to the debt or equity provider or an Affiliate of the debt or equity provider.

3. Do Not Pay: The CDFI Fund will contact the Do Not Pay Business Center to ensure that an Applicant, its Controlling Entity, and any Affiliate(s) are not prohibited from receiving federal funds. An Applicant, its Controlling Entity, and any Affiliate(s) reported by the Do Not Pay Business Center as having a pending or delinquent debt to the Federal government will be required to demonstrate that it has resolved such pending or delinquent debt. Applicants that fail to demonstrate resolution of such pending or delinquent debt to the Federal government will be found ineligible to receive an allocation.

4. Controlling Entities: An organization that was a Controlling Entity to an Allocatee in a prior round(s) and subsequently separated from that Allocatee, as a result of an amendment to the Allocation Agreement(s), may not claim the NMTC-related track record of such Allocatee.

5. Prior award recipients or Allocatees: Applicants must be aware that success in a prior application or allocation round of any of the CDFI Fund's programs is not indicative of success under this NOAA. For purposes of this NOAA, and eligibility determinations, the CDFI Fund will consider an Affiliate to be any entity that meets the definition of Affiliate as defined in the NMTC Allocation Application materials, or any entity otherwise identified as an Affiliate by the Applicant in its NMTC Allocation Application materials.

Prior award recipients of any CDFI Fund program are eligible to apply under this NOAA, except as follows:

(a) Prior Allocatees and Qualified Equity Investment (QEI) issuance and Qualified Low Income Community Investment (QLICI) requirements: CDEs that are Allocatees under the CY 2015–16 to the CY 2020 rounds must finalize at least the percentage of QEIs noted in Table 2 for each NMTC Allocation round and use at least the percentage of those QEIs designated in Schedule 1, section 3.2(j) of their Allocation Agreements to make QLICIs by the deadline in Table 1. CDEs that are Allocatees under the CY 2015–16 to the CY 2020 allocation rounds and CDEs that are Allocatees designated as Rural CDEs in their CY 2019 and/or CY 2020 Allocation Agreements must meet the following thresholds.

TABLE 2—QEI ISSUANCE AND QLICI REQUIREMENTS

Prior round allocation	Finalized QEI requirement %	Rural CDE finalized QEI requirement %	QLICIs
CY 2015–16	100	100	As stated in Section 3.2(j) of the applicable Allocation Agreement.
CY 2017	90	90	
CY 2018	70	70	
CY2019	40	40	
CY 2020	20	0	

In addition to the requirements noted above, a CDE is not eligible to receive an NMTC Allocation pursuant to this NOAA if an Affiliate of the Applicant is a prior Allocatee and has not met the minimum QEI issuance and QLICI thresholds as set forth in Table 2 for Allocatees in the prior allocation rounds of the NMTC Program.

For purposes of this section of the NOAA, the CDFI Fund will only recognize as ''finalized'' those QEIs that have been properly reported in AMIS Allocation and QEI Tracking System for Qualified Equity Investments (AQEIs) by the deadline in Table 1. Allocatees and their Subsidiary Allocatees, if any, are advised to access AMIS to record each QEI that they issue to an investor in exchange for cash. Furthermore, the CDFI Fund will only recognize QLICIs that have been certified in AMIS by the deadline in Table 1. Instructions on recording a QEI and QLICIs in AMIS are available at *https://www.cdfifund.gov/amisreporting.* Applicants may be required, upon notification from the CDFI Fund, to submit documentation to substantiate the required QEI issuance and QLICI thresholds.

Any prior Allocatee that requires action by the CDFI Fund (*i.e.,* certifying a subsidiary entity as a CDE; adding a subsidiary CDE to an Allocation Agreement; etc.) in order to meet the

QEI issuance requirements above must submit a CDE Certification Application for Subsidiary CDEs and/or Allocation Agreement amendment requests by the respective deadlines in Table 1, in order to guarantee that the CDFI Fund completes all necessary approvals prior to the QEI issuance deadline in Table 1. Applicants for Subsidiary CDE certification may obtain information regarding CDE certification and the CDE Certification Application process in AMIS on the CDFI Fund's website at *https://www.cdfifund.gov/programs-training/certification/cde/Pages/default.aspx.*

(b) Pending determination of noncompliance or default: If an Applicant is a prior award recipient or Allocatee under any CDFI Fund program and if: (i) It has demonstrated noncompliance with a previous assistance or award agreement or default under a previous Allocation Agreement; and (ii) the entity has been given a

timeframe to cure the noncompliance or default, the CDFI Fund will consider the Applicant's application under this NOAA during the time period given for the entity to cure the noncompliance or default, and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default. Further, if an Affiliate of the Applicant is a prior CDFI Fund award recipient or Allocatee and if such entity: (i) Has demonstrated noncompliance with a previous assistance or award agreement or default under a previous Allocation Agreement; and (ii) the entity has been given a timeframe to cure the noncompliance or default, then the CDFI Fund will consider the Applicant's application under this NOAA during the time period given for the entity to cure the noncompliance or default, and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default.

(c) Noncompliance or default status: The CDFI Fund will not consider an application submitted by an Applicant that is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund program if, as of the application deadline of this NOAA: (i) The CDFI Fund has made a final determination that such Applicant is noncompliant with a previously executed assistance or award agreement, or in default of a previously executed Allocation Agreement; and (ii) the CDFI Fund has provided written notification of such final determination to the Applicant; and (iii) the default occurs during the time period beginning 12 months prior to the application deadline and ending with the CY 2021 allocation award announcement. Further, the CDFI Fund will not consider an application submitted by an Applicant with an Affiliate that is a prior award recipient or Allocatee under any CDFI Fund Program if, as of the application deadline of this NOAA: (i) the CDFI Fund has made a final determination that such Affiliate is noncompliant with a previously executed assistance or award agreement, or in default of a previously executed Allocation Agreement; (ii) the CDFI Fund has provided written notification of such final determination to the Affiliate; and (iii) the noncompliance or default occurs during the time period beginning 12 months prior to the application deadline and ending with the CY 2021 allocation award announcement.

(d) Contacting the CDFI Fund: Accordingly, Applicants that are prior award recipients and/or Allocatees under any CDFI Fund program are advised to comply with the requirements specified in assistance, allocation and/or award agreement(s). All outstanding reports and compliance questions should be directed to the Office of Certification Policy and Evaluation (OCPE) through a Service Request initiated in AMIS. Requests submitted less than 30 calendar days prior to the application deadline may not receive a response before the application deadline.

The CDFI Fund will respond to Applicants' reporting, compliance and CDE certification inquiries Monday through Friday, between the hours of 9:00 a.m. and 5:00 p.m. ET, starting the date of publication of this NOAA through the ''Last date to contact CDFI Fund staff'' specified in Table 1. Inquiries received after the ''Last date to contact the CDFI Fund staff'' will be responded to after the Allocation Application deadline.

6. Failure to accurately respond to a question in the Assurances and Certifications section of the application, submit the required written explanation, or provide any updates: In its sole discretion, the CDFI Fund may deem the Applicant's application ineligible, if the CDFI Fund determines that the Applicant inaccurately responded to a question, accurately responded to a question, but failed to submit a required written explanation, or failed to notify the CDFI Fund of any changes to the information submitted between the date of application and the date the Allocatee executes the Allocation Agreement, with respect to the Assurances and Certifications. In making this determination, the CDFI Fund will take into consideration, among other factors, the materiality of the question, the substance of any supplemental responses provided, and whether the information in the Applicant's supplemental responses would have a material adverse effect on the Applicant, its financial condition or its ability to perform under an Allocation Agreement, should the Applicant receive an allocation.

7. Entities that propose to transfer NMTCs to Subsidiary CDEs: Both for-profit and non-profit CDEs may apply for NMTC Allocation authority, but only a for-profit CDE is permitted to provide NMTCs to its investors. A non-profit Applicant wishing to apply for an NMTC Allocation must demonstrate, prior to entering into an Allocation Agreement with the CDFI Fund, that: (i) It controls one or more Subsidiary CDEs that are for-profit entities; and (ii) it intends to transfer the full amount of any NMTC Allocation it receives to said Subsidiary CDEs.

An Applicant wishing to transfer all or a portion of its NMTC Allocation to a Subsidiary CDE is not required to create the Subsidiary prior to submitting an NMTC Allocation Application to the CDFI Fund. However, the Subsidiary entities must be certified as CDEs by the CDFI Fund, and enjoined as parties to the Allocation Agreement at closing or by amendment to the Allocation Agreement after closing.

The CDFI Fund requires a non-profit Applicant to submit a CDE Certification Application to the CDFI Fund on behalf of at least one for-profit Subsidiary within 45 days after the non-profit Applicant receives notification from the CDFI Fund of its allocation award, as such Subsidiary must be certified as a CDE prior to entering into an Allocation Agreement with the CDFI Fund. The CDFI Fund reserves the right to rescind the award if a non-profit Applicant that does not already have a certified for-profit Subsidiary CDE fails to submit a CDE Certification Application for one or more for-profit Subsidiaries within 45 days of the date it receives notification from the CDFI Fund of its allocation award.

8. Entities that submit applications together with Affiliates; applications from common enterprises:

(a) As part of the Allocation Application review process, the CDFI Fund will evaluate whether Applicants are Affiliates, as such term is defined in the Allocation Application. If an Applicant and its Affiliate(s) wish to submit Allocation Applications, they must do so collectively, in one application; an Applicant and its Affiliate(s) may not submit separate Allocation Applications. If Affiliated entities submit multiple applications, the CDFI Fund will reject all such applications received, except for those state-owned or state-controlled governmental Affiliated entities. In the case of state-owned or state-controlled governmental entities, the CDFI Fund may accept applications submitted by different government bodies within the same state, but only to the extent the CDFI Fund determines that the business strategies and/or activities described in such applications, submitted by separate entities, are distinctly dissimilar and/or are operated and/or managed by distinctly dissimilar personnel, including staff, board members and identified consultants. In such cases, the CDFI Fund reserves the right to limit award amounts to such entities to ensure that the entities do not collectively receive more than the $100 million cap.

If the CDFI Fund determines that the applications submitted by different

government bodies in the same state are not distinctly dissimilar and/or operated and/or managed by distinctly dissimilar personnel, it will reject all such applications.

(b) For purposes of this NOAA, the CDFI Fund will also evaluate whether each Applicant is operated or managed as a ''common enterprise'' with another Applicant in this Allocation Round using the following indicia, among others: (i) whether different Applicants have the same individual(s), including the Authorized Representative, staff, board members and/or consultants, involved in day-to-day management, operations and/or investment responsibilities; (ii) whether the Applicants have business strategies and/or proposed activities that are so similar or so closely related that, in fact or effect, they may be viewed as a single entity; and/or (iii) whether the applications submitted by separate Applicants contain significant narrative, textual or other similarities such that they may, in fact or effect, be viewed as substantially identical applications. In such cases, the CDFI Fund will reject all applications received from such entities.

(c) Furthermore, an Applicant that receives an NMTC Allocation in this Allocation Round (or its Subsidiary Allocatee) may not become an Affiliate of or member of a common enterprise (as defined above) with another Applicant that receives an NMTC Allocation in this Allocation Round (or its Subsidiary Allocatee) at any time after the submission of an Allocation Application under this NOAA. This prohibition, however, generally does not apply to entities that are commonly controlled solely because of common ownership by QEI investors. This requirement will also be a term and condition of the Allocation Agreement (see Section VI.B of this NOAA and additional application guidance materials on the CDFI Fund's website at *https://www.cdfifund.gov* for more details).

9. Entities created as a series of funds: An Applicant whose business structure consists of an entity with a series of funds must apply for CDE certification for each fund. If such an Applicant represents that it is properly classified for Federal tax purposes as a single partnership or corporation, it may apply for CDE certification as a single entity. If an Applicant represents that it is properly classified for Federal tax purposes as multiple partnerships or corporations, then it must submit a CDE Certification Application for the Applicant and each fund it would like to participate in the NMTC Program, and each fund must be separately certified as a CDE. Applicants should note, however, that receipt of CDE certification as a single entity or as multiple entities is not a determination that an Applicant and its related funds are properly classified as a single entity or as multiple entities for Federal tax purposes. Regardless of whether the series of funds is classified as a single partnership or corporation or as multiple partnerships or corporations, an Applicant may not transfer any NMTC Allocations it receives to one or more of its funds unless the fund is a certified CDE that is a Subsidiary of the Applicant, enjoined to the Allocation Agreement as a Subsidiary Allocatee.

10. Entities that are Bank Enterprise Award Program (BEA Program) award recipients: An insured depository institution investor (and its Affiliates and Subsidiaries) may not receive an NMTC Allocation in addition to a BEA Program award for the same investment in a CDE. Likewise, an insured depository institution investor (and its Affiliates and Subsidiaries) may not receive a BEA Program award in addition to an NMTC Allocation for the same investment in a CDE.

IV. Application and Submission Information

A. Address to request application package: Applicants must submit applications electronically under this NOAA, through the CDFI Fund's AMIS. Following the publication of this NOAA, the CDFI Fund will make the electronic Allocation Application available on its website at *https://www.cdfifund.gov.*

B. Application content requirements: Detailed application content requirements are found in the application related to this NOAA. Applicants must submit all materials described in and required by the application by the applicable deadlines. Applicants will not be afforded an opportunity to provide any missing materials or documentation, except, if necessary and at the request of the CDFI Fund. Electronic applications must be submitted solely by using the format made available via AMIS. Additional information, including instructions relating to the submission of supporting information (*e.g.,* the Controlling Entity's representative signature page, Assurances and Certifications supporting documents, investor letters, organizational charts), is set forth in further detail in the CY 2021 NMTC Application—AMIS Navigation Guide for this Allocation Round. An application must include a valid and current Employer Identification Number (EIN) issued by the Internal Revenue Service (IRS) and assigned to the Applicant and, if applicable, its Controlling Entity. Electronic applications without a valid EIN are incomplete and cannot be transmitted to the CDFI Fund. For more information on obtaining an EIN, please contact the IRS at (800) 829–4933 or *www.irs.gov.* Do not include any personal Social Security Numbers as part of the application.

C. NMTC Application Registration (Application Registration): CY 2021 Allocation Round Applicants are first required to complete and save the Application Registration section of the NMTC Allocation Application in AMIS by the Application Registration deadline in order to be able to submit the remaining sections of the CY 2021 Allocation Application by the Application deadline. Applicants that do not complete and save the Application Registration by the Application Registration deadline, will not be able to subsequently submit a CY 2021 Allocation Application in AMIS.

An Applicant may not submit more than one application in response to this NOAA. In addition, as stated in Section III.A.6 of this NOAA, an Applicant and its Affiliates must collectively submit only one Allocation Application; an Applicant and its Affiliates may not submit separate Allocation Applications except as outlined in Section III.A.6 above. Once an application is submitted, an Applicant will not be allowed to change any element of its application.

D. Form of application submission: Applicants may only submit applications under this NOAA electronically via AMIS, the CDFI Fund's Award Management Information System. Applications and required attachments sent by mail, facsimile, or email will not be accepted. Submission of an electronic application will facilitate the processing and review of applications and the selection of Allocatees; further, it will assist the CDFI Fund in the implementation of electronic reporting requirements.

Electronic applications must be submitted solely by using the CDFI Fund's website and must be sent in accordance with the submission instructions provided in the CY 2021 NMTC Application—AMIS Navigation Guide for this Allocation Round. AMIS will only permit the submission of applications in which all required questions and tables are fully completed. Additional information, including instructions relating to the submission of supporting information (*e.g.,* the Controlling Entity's representative signature page, Assurances and Certifications

supporting documents, investor letters, and organizational charts) is set forth in further detail in the CY 2021 NMTC Application—AMIS Navigation Guide for this Allocation Round.

E. Application submission dates and times: Electronic applications must be received by the Allocation Application deadline in Table 1. Electronic applications cannot be transmitted or received after Allocation Application deadline in Table 1. In addition, Applicants must electronically submit supporting information (*e.g.,* the Controlling Entity's representative signature page, investor letters, and organizational charts). The Controlling Entity's representative signature page, Assurances and Certifications supporting documents, investor letters, and organizational charts must be submitted on or before the Application deadline in Table 1. For details, see the instructions provided in the CY 2021 NMTC Application—AMIS Navigation Guide for this Allocation Round on the CDFI Fund's website.

Applications and other required documents received after this date and time will be rejected. Please note that the document submission deadlines in this NOAA and/or the Allocation Application are strictly enforced.

F. Intergovernmental Review: Not applicable.

G. Funding Restrictions: For allowable uses of investment proceeds related to an NMTC Allocation, please see 26 U.S.C. 45D and the final regulations issued by the Internal Revenue Service (26 CFR 1.45D–1, published December 28, 2004 and as amended) and related guidance. Please see Section I, above, for the Programmatic Changes of this NOAA.

H. Paperwork Reduction: Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. Pursuant to the Paperwork Reduction Act, the application has been assigned the following control number: 1559–0016.

V. Application Review Information

A. Review and selection process: All Allocation Applications will be reviewed for eligibility and completeness. To be complete, the application must contain, at a minimum, all information described as required in the application form. An incomplete application will be rejected. Once the application has been determined to be eligible and complete, the CDFI Fund will conduct the substantive review of each application in two parts (Phase 1 and Phase 2) in accordance with the criteria and procedures generally described in this NOAA and the Allocation Application.

In Phase 1, two reviewers will evaluate and score the Business Strategy and Community Outcomes sections of each application. An Applicant must exceed a minimum overall aggregate base score threshold and exceed a minimum aggregate section score threshold in each scored section in order to advance from the Phase 1 to the Phase 2 part of the substantive review process. In Phase 2, the CDFI Fund will rank Applicants and determine the dollar amount of allocation authority awarded in accordance with the procedures set forth below.

B. Criteria:

1. Business Strategy (25-point maximum):

(a) When assessing an Applicant's business strategy, reviewers will consider, among other things: The Applicant's products, services and investment criteria; a pipeline of potential business loans or investments consistent with an Applicant's request for an NMTC Allocation; the prior performance of the Applicant or its Controlling Entity, particularly as it relates to making similar kinds of investments as those it proposes to make with the proceeds of QEIs; the Applicant's prior performance in providing capital or technical assistance to disadvantaged businesses or communities; and the extent to which the Applicant intends to make QLICIs in one or more businesses in which persons unrelated to the entity hold a majority equity interest.

Under the Business Strategy criterion, an Applicant will generally score well to the extent that it will deploy debt or investment capital in products or services which are flexible or non-traditional in form and on better terms than available in the marketplace. An Applicant will also score well to the extent that, among other things: (i) It has identified a set of clearly-defined potential borrowers or investees; (ii) it describes the due diligence it will conduct prior to making QLICIs to determine whether a QALICB will remain financially viable and operational; (iii) it has a track record of successfully deploying loans or equity investments and providing services similar to those it intends to provide with the proceeds of QEIs; (iv) its projected dollar volume of NMTC Allocation deployment is supported by its track record of deployment; and (v) in the case of an Applicant proposing to purchase loans from CDEs, the Applicant will require the CDE selling such loans to re-invest the proceeds of the loan sale to provide additional products and services to Low-Income Communities.

(b) Priority Points: In addition, as provided by IRC § 45D(f)(2), the CDFI Fund will ascribe additional points to entities that meet one or both of the statutory priorities. First, the CDFI Fund will give up to five additional points to any Applicant that has a record of having successfully provided capital or technical assistance to disadvantaged businesses or communities. Second, the CDFI Fund will give five additional points to any Applicant that intends to satisfy the requirement of IRC § 45D(b)(1)(B) by making QLICIs in one or more businesses in which persons unrelated (within the meaning of IRC § 267(b) or IRC § 707(b)(1)) to an Applicant (and the Applicant's Subsidiary CDEs, if the Subsidiary Allocatee makes the QLICI) hold the majority equity interest. Applicants may earn points for one or both statutory priorities. Thus, Applicants that meet the requirements of both priority categories can receive up to a total of ten additional points. A record of having successfully provided capital or technical assistance to disadvantaged businesses or communities may be demonstrated either by the past actions of an Applicant itself or by its Controlling Entity (*e.g.,* where a new CDE is established by a nonprofit corporation with a history of providing assistance to disadvantaged communities). An Applicant that receives additional points for intending to make investments in unrelated businesses and is awarded an NMTC Allocation must meet the requirements of IRC § 45D(b)(1)(B) by investing substantially all of the proceeds from its QEIs in unrelated businesses. The CDFI Fund will include an Applicant's priority points when ranking Applicants during Phase 2 of the review process, as described below.

2. Community Outcomes (25-point maximum): In assessing the potential benefits to Low-Income Communities that may result from the Applicant's proposed investments, reviewers will consider, among other things, the degree to which the Applicant is likely to: (i) achieve significant and measurable community development outcomes in its Low-Income Communities; (ii) invest in particularly economically distressed markets including areas identified in the Allocation Application such as Federally designated Opportunity Zones; (iii) engage with local communities regarding investments; and (iv) involve community

representatives in the governing board and/or advisory board in approving investment criteria or decisions.

An Applicant will generally score well under this section to the extent that, among other things: (a) It will generate clear and well supported community development outcomes; (b) it has a track record of producing quantitative and qualitative community outcomes that are similar to those projected to be achieved with an NMTC Allocation; (c) it is working in particularly economically distressed or otherwise underserved communities; (d) its activities are part of a broader community or economic development strategy; (e) it demonstrates a track record of community engagement around past investment decisions; and (f) it ensures that an NMTC investment into a project or business is supported by and will be beneficial to Low-Income Persons and residents of Low-Income Communities.

C. Phase 2 Evaluation:

1. Application Ranking and Anomaly Reviews: Using the numeric scores from Phase 1, Applicants are ranked on the basis of each Applicant's combined scores in the Business Strategy and Community Outcomes sections of the application plus one half of the priority points. If, in the case of a particular application, a reviewer's total base score or section score(s) (in one or more of the two application scored sections) varies significantly from the other reviewer's total base scores or section scores for such application, the CDFI Fund may, in its sole discretion, obtain the evaluation and numeric scoring of an additional third reviewer to determine whether the anomalous score should be replaced with the score of the additional third reviewer.

2. Late Reports: In the case of an Applicant or any Affiliates that have previously received an award or NMTC Allocation from the CDFI Fund through any CDFI Fund program, the CDFI Fund will deduct up to five points from the Applicant's rank score for the Applicant's (or its Affiliate's) failure to meet any of the reporting deadlines set forth in any assistance, award or Allocation Agreement(s), if the reporting deadlines occurred during the period from October 29, 2019 to the application deadline in this NOAA.

3. Prior Year Allocatees: In the case of Applicants (or their Affiliates) that are prior year Allocatees, the CDFI Fund will review the activities of the prior year Allocatee to determine whether the entity has: (a) Effectively utilized its prior-year NMTC Allocations in a manner generally consistent with the representations made in the relevant Allocation Application (including, but not limited to, the proposed product offerings, business type, fees and markets served (*i.e.* service area) and notable relationships); (b) issued QEIs and closed QLICIs in a timely manner; and (c) substantiated a need for additional NMTC Allocation authority. The CDFI Fund will use this information in determining whether to reject or reduce the allocation award amount of its NMTC Allocation Application.

An Applicant will be evaluated more favorably under Part V. of the Application to the extent that it clearly explains: (i) how it ensures that the NMTCs allocated to QALICBs did not exceed the amount necessary to assure QALICB feasibility; (ii) the community outcomes or benefits that were generated as a result of the transaction; (iii) source(s) and amount(s) of leveraged debt from all sources; (iv) the NMTC-related fees and third-party expenses paid by the *QALICB* or the *QALICB's Affiliates*, including actions taken to control expenses paid by *QALICBs* and investors; and (v) quantifies the value of the investment acquired by the *QALICBs* at the end of the seven-year credit period, to the extent the *Applicant's* past transactions have been structured to allow *QALICBs* to acquire a portion of *QLICIs* at the end of the seven-year credit period. An Applicant will also be evaluated favorably to the extent the activities undertaken with the NMTC dollars are consistent with the business strategy presented in the relevant Allocation Application (*e.g.* product offerings; business type; fees and markets served; notable relationships, etc.).

4. Management Capacity: In assessing an Applicant's management capacity, the CDFI Fund will consider, among other things, the current and planned roles, as well as qualifications of the Applicant's (and Controlling Entity's, if applicable): principals; board members; management team; and other essential staff or contractors, with specific focus on: experience in providing loans; equity investments or financial counseling and other services, including activities similar to those described in the Applicant's business strategy; asset management and risk management experience; experience with fulfilling compliance requirements of other governmental programs, including other tax credit programs; and the Applicant's (or its Controlling Entity's) financial health. CDFI Fund evaluators will also consider the extent to which an Applicant has protocols in place to ensure ongoing compliance with NMTC Program requirements and the Applicant's projected income and expenses related to managing an NMTC Allocation.

An Applicant will be generally evaluated more favorably under this section to the extent that its management team or other essential personnel have experience in: (a) Identifying and underwriting loans and/or equity investments or providing financial counseling and other services in Low-Income Communities, if applicable, particularly those likely to be served with QLICIs from the Applicant; (b) asset and risk management; and (c) fulfilling government compliance requirements, particularly tax credit program compliance. An Applicant will also be evaluated favorably to the extent it clearly explains its due diligence when providing businesses with financing or investment; demonstrates strong financial health and a high likelihood of remaining a going-concern, including support from the Controlling Entity, if applicable; it clearly explains its NMTC fees as well as levels of income and expenses; has policies and systems in place to ensure portfolio quality, ongoing compliance with NMTC Program requirements; and, if it is a Federally-insured financial institution, has its most recent Community Reinvestment Act (CRA) rating as ''outstanding.''

5. Capitalization Strategy: When assessing an Applicant's capitalization strategy, the CDFI Fund will consider, among other things: The key personnel of the Applicant (or Controlling Entity) and their track record of raising capital, particularly from for-profit investors; the extent to which the Applicant has secured investments or commitments to invest in NMTC (if applicable), or indications of investor interest commensurate with its requested amount of NMTC Allocations, or, if a prior Allocatee, the track record of the Applicant or its Affiliates in raising Qualified Equity Investments in the past five years; the Applicant's strategy for identifying additional investors, if necessary, including the Applicant's (or its Controlling Entity's) prior performance with raising equity from investors, particularly for-profit investors; the distribution of the economic benefits of the tax credit; and the extent to which the Applicant intends to invest the proceeds from the aggregate amount of its QEIs at a level that exceeds the requirements of IRC § 45D(b)(1)(B) and the IRS regulations.

An Applicant will be evaluated more favorably under this section to the extent that: (a) It or its Controlling Entity demonstrate a track record of

raising investment capital; (b) it has secured investor commitments, or has a reasonable strategy for obtaining such commitments, or, if it or its Affiliates is a prior Allocatee with a track record in the past five years of raising Qualified Equity Investments and; (c) it generally demonstrates that the economic benefits of the tax credit will be passed through to a QALICB; and (d) it intends to invest the proceeds from the aggregate amount of its QEIs at a level that exceeds the requirements of IRC § 45D(b)(1)(B) and the IRS regulations. In the case of an Applicant proposing to raise investor funds from organizations that also will identify or originate transactions for the Applicant or from Affiliated entities, said Applicant will be evaluated more favorably to the extent that it will offer products with more favorable rates or terms than those currently offered by its investor(s) or Affiliated entities and/or will target its activities to areas of greater economic distress than those currently targeted by the investor or Affiliated entities.

6. Contacting Applicants: As a part of the substantive review process, the CDFI Fund may permit the NMTC Allocation recommendation panel member(s) to request information from Applicants for the sole purpose of obtaining, clarifying or confirming application information or omission of information. In no event shall such contact be construed to permit an Applicant to change any element of its application. At this point in the process, an Applicant may be required to submit additional information about its application in order to assist the CDFI Fund with its final evaluation process. If the Applicant (or the Controlling Entity or any Affiliate) has previously been awarded an NMTC Allocation, the CDFI Fund may also request information on the use of those NMTC Allocations, to the extent that this information has not already been reported to the CDFI Fund. Such requests must be responded to within the time parameters set by the CDFI Fund. The selecting official(s) will make a final allocation determination based on an Applicant's file, including, without limitation, eligibility under IRC § 45D, the reviewers' scores and the amount of NMTC Allocation authority available.

7. Award Decisions: The CDFI Fund will award allocations in descending order of the final rank score, subject to Applicants meeting all other eligibility requirements; provided, however, that the CDFI Fund, in its sole discretion, reserves the right to reject an application and/or adjust award amounts as appropriate based on information obtained during the review process.

D. Allocations serving non-metropolitan counties: As provided for under Section 102(b) of the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432), the CDFI Fund shall ensure that Non-Metropolitan counties receive a proportional allocation of QEIs under the NMTC Program. The CDFI Fund will endeavor to ensure that 20 percent of the QLICIs to be made using QEI proceeds are invested in Non-Metropolitan counties. In addition, the CDFI Fund will ensure that the proportion of Allocatees that are Rural CDEs is, at a minimum, equal to the proportion of Applicants in the highly qualified pool that are Rural CDEs. A Rural CDE is one that has a track record of at least three years of direct financing experience, has dedicated at least 50 percent of its direct financing dollars to Non-Metropolitan counties over the past five years, and has committed that at least 50 percent of its NMTC financing dollars with this NMTC Allocation will be deployed in such areas. Non-Metropolitan counties are counties not contained within a Metropolitan Statistical Area, as such term is defined in OMB Bulletin No. 10–02 (Update of Statistical Area Definitions and Guidance on Their Uses) and applied using 2010 census tracts.

Applicants that meet the minimum scoring thresholds will be advanced to Phase 2 review and will be provided with ''preliminary'' awards, in descending order of final rank score, until the available allocation authority is fulfilled. Once these ''preliminary'' award amounts are determined, the CDFI Fund will then analyze the Allocatee pool to determine whether the two Non-Metropolitan proportionality objectives have been met.

The CDFI Fund will first examine the ''preliminary'' awards and Allocatees to determine whether the percentage of Allocatees that are Rural CDEs is, at a minimum, equal to the percentage of Applicants in the highly qualified pool that are Rural CDEs. If this objective is not achieved, the CDFI Fund will provide awards to additional Rural CDEs from the highly qualified pool, in descending order of their final rank score, until the appropriate percentage balance is achieved. In order to accommodate the additional Rural CDEs in the Allocatee pool within the available NMTC Allocation limitations, a formula reduction may be applied as uniformly as possible to the allocation amount for all Allocatees in the pool that have not committed to investing a minimum of 20 percent of their QLICIs in Non-Metropolitan counties.

The CDFI Fund will then determine whether the pool of Allocatees will, in the aggregate, invest at least 20 percent of their QLICIs (as measured by dollar amount) in Non-Metropolitan counties. The CDFI Fund will first apply the ''minimum'' percentage of QLICIs that Allocatees indicated in their applications would be targeted to Non-Metropolitan areas to the total NMTC Allocation award amount of each Allocatee (less whatever percentage the Allocatee indicated would be retained for non-QLICI activities), and total these figures for all Allocatees. If this aggregate total is greater than or equal to 20 percent of the QLICIs to be made by the Allocatees, then the pool is considered balanced and the CDFI Fund will proceed with the NMTC Allocation process. However, if the aggregate total is less than 20 percent of the QLICIs to be made by the Allocatees, the CDFI Fund will consider requiring any or all of the Allocatees to direct up to the ''maximum'' percentage of QLICIs that the Allocatees indicated would be targeted to Non-Metropolitan counties, taking into consideration their track record and ability to deploy dollars in Non-Metropolitan counties. If the CDFI Fund cannot meet the goal of 20 percent of QLICIs in Non-Metropolitan counties by requiring any or all Allocatees to commit up to the maximum percentage of QLICIs that they indicated would be targeted to Non-Metropolitan counties, the CDFI Fund may add additional highly qualified Rural CDEs (in descending order of final rank score) to the Allocatee pool. In order to accommodate any additional Allocatees within the allocation limitations, a formula reduction will be applied as uniformly as possible, to the allocation amount for all Allocatees in the pool that have not committed to investing a minimum of 20 percent of their QLICIs in Non-Metropolitan counties.

E. Right of rejection: The CDFI Fund reserves the right to reject any NMTC Allocation Application in the case of a prior CDFI Fund award recipient, if such Applicant has failed to comply with the terms, conditions, and other requirements of the prior or existing assistance or award agreement(s) with the CDFI Fund. The CDFI Fund reserves the right to reject any NMTC Allocation Application in the case of a prior CDFI Fund Allocatee, if such Applicant has failed to comply with the terms, conditions, and other requirements of its prior or existing Allocation Agreement(s) with the CDFI Fund. The CDFI Fund reserves the right to reject any NMTC Allocation Application in the case of any Applicant, if an Affiliate

of the Applicant has failed to meet the terms, conditions and other requirements of any prior or existing assistance agreement, award agreement or Allocation Agreement with the CDFI Fund.

The CDFI Fund reserves the right to reject or reduce the allocation award amount of any NMTC Allocation Application in the case of a prior Allocatee, if such Applicant has failed to use its prior NMTC Allocation(s) in a manner that is generally consistent with the business strategy (including, but not limited to, the proposed product offerings, business type, fees, markets served (*i.e.* service area), and notable relationships) set forth in the Allocation Application(s) related to such prior NMTC Allocation(s) or such Applicant has been found by the IRS to have engaged in a transaction or series of transactions designed to achieve a result that is inconsistent with the purposes of IRC § 45D. The CDFI Fund also reserves the right to reject or reduce the allocation award amount of any NMTC Allocation Application in the case of an Affiliate of the Applicant that is a prior Allocatee and has failed to use its prior NMTC Allocation(s) in a manner that is generally consistent with the business strategy (including, but not limited to, the proposed product offerings, business type, fees, markets served (*i.e.,* service area), and notable relationships) set forth in the Allocation Application(s) related to such prior NMTC Allocation(s) or has been found by the IRS to have engaged in a transaction or series of transactions designed to achieve a result that is inconsistent with the purposes of IRC § 45D.

The CDFI Fund reserves the right to reject an NMTC Allocation Application if information (including, but not limited to, administrative errors; submission of inaccurate information; or omission of information) comes to the attention of the CDFI Fund that adversely affects an Applicant's eligibility for an award, adversely affects the CDFI Fund's evaluation or scoring of an application, adversely affects the CDFI Fund's prior determinations of CDE certification, or indicates fraud or mismanagement on the part of an Applicant, its Affiliate(s), or the Controlling Entity, if such fraud or mismanagement by the Affiliate(s) or Controlling Entity would hinder the Applicant's ability to perform under the Allocation Agreement. If the CDFI Fund determines that any portion of the application is incorrect in any material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the application.

The CDFI Fund reserves the right to reject any NMTC Allocation Application if additional information is obtained that, after further due diligence and in the discretion of the CDFI Fund, would hinder the Applicant's ability to effectively perform under the Allocation Agreement.

In the case of Applicants (or the Controlling Entity, or Affiliates) that are regulated or receive oversight by the Federal government or a state agency (or comparable entity), the CDFI Fund may request additional information from the Applicant regarding Assurances and Certifications or other information about the ability of the Applicant to effectively perform under the Allocation Agreement. The NMTC Allocation recommendation panel or selecting official(s) reserve(s) the right to consult with and take into consideration the views of the appropriate Federal banking and other regulatory agencies. In the case of Applicants (or Affiliates of Applicants) that are also Small Business Investment Companies, Specialized Small Business Investment Companies or New Markets Venture Capital Companies, the CDFI Fund reserves the right to consult with and take into consideration the views of the Small Business Administration. An Applicant that is or is affiliated with an insured depository institution will not be awarded an NMTC Allocation if it has a composite rating of ''5'' on its most recent examination, performed in accordance with the Uniform Financial Institutions Rating System.

Furthermore, the CDFI Fund will not award an NMTC Allocation to an Applicant that is an insured depository institution or is an Affiliate of an insured depository institution, if during the time period beginning with the application deadline and ending with the execution of the CY 2021 Allocation Agreement; the Applicant received any of the following: 1. CRA assessment rating of below ''Satisfactory'' on its most recent examination; 2. A going concern opinion on its most recent audit; or 3. A Prompt Corrective Action directive from its regulator.

The CDFI Fund reserves the right to conduct additional due diligence on all Applicants, as determined reasonable and appropriate by the CDFI Fund, in its sole discretion, related to the Applicant, Affiliates, the Applicant's Controlling Entity and the officers, directors, owners, partners and key employees of each. This includes the right to consult with the IRS if the Applicant (or the Controlling Entity, or Affiliates) has previously been awarded an NMTC Allocation.

F. Allocation Announcement: Each Applicant will be informed of the CDFI Fund's award decision through an electronic notification whether selected for an allocation or not selected for an allocation, which may be for reasons of application incompleteness, ineligibility, or substantive issues. Eligible Applicants that are not selected for an allocation based on substantive issues will likely be given the opportunity to receive feedback on their applications. This feedback will be provided in a format and within a timeframe to be determined by the CDFI Fund, based on available resources.

The CDFI Fund further reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If said changes materially affect the CDFI Fund's award decisions, the CDFI Fund will provide information regarding the changes through the CDFI Fund's website.

The CDFI Fund reserves the right, in its sole discretion, to rescind an allocation made under this NOAA, should an Allocatee be identified as ineligible due to pending or delinquent debt to the Federal government in the Do Not Pay database.

There is no right to appeal the CDFI Fund's NMTC Allocation decisions. The CDFI Fund's NMTC Allocation decisions are final.

VI. Award Administration Information

A. Allocation Award Compliance

1. Failure to meet reporting requirements: If an Allocatee, or an Affiliate of an Allocatee, is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund program and is not current on the reporting requirements set forth in the previously executed assistance, allocation, or award agreement(s) as of the date the CDFI Fund provides notification of an NMTC Allocation award or thereafter, the CDFI Fund reserves the right, in its sole discretion, to reject the application, delay entering into an Allocation Agreement, and/or impose limitations on an Allocatee's ability to issue QEIs to investors until said prior award recipient or Allocatee is current on the reporting requirements in the previously executed assistance, allocation, or award agreement(s). Please note that the automated systems the CDFI Fund uses for receipt of reports submitted electronically typically acknowledges only a report's receipt; such an acknowledgment does not warrant that the report received was complete and therefore met reporting requirements.

2. Pending determination of noncompliance or default: If an

Allocatee is a prior award recipient or Allocatee under any CDFI Fund program and if: (i) It has demonstrated noncompliance with a previous assistance or award agreement or a default under an Allocation Agreement; and (ii) the entity has been given a timeframe to cure the noncompliance or default, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee's ability to issue QEIs to investors, during the time period given for the entity to cure the noncompliance or default and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default, and determination of remedies, if applicable, in the sole determination of the CDFI Fund. Further, if an Affiliate of an Allocatee is a prior CDFI Fund award recipient or Allocatee and if such entity: (i) Has demonstrated noncompliance under a previous assistance or award agreement or default under a previous Allocation Agreement; and (ii) the entity has been given a timeframe to cure the noncompliance or default, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee's ability to issue QEIs to investors, during the time period given for the entity to cure the noncompliance or default and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default, and determination of remedies, if applicable, in the sole determination of the CDFI Fund. If the prior award recipient or Allocatee in question is unable to satisfactorily resolve the issues of noncompliance or default, in the sole determination of the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the award notification made under this NOAA.

3. Determination of noncompliance or default status: If prior to entering into an Allocation Agreement through this NOAA, the CDFI Fund has made a final determination that an Allocatee that is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund program is (i) noncompliant with a previously executed assistance or award agreement, or is in default of a previously executed Allocation Agreement; (ii) the CDFI Fund has provided written notification of such determination to such organization; and (iii) the noncompliance or default occurs during the time period beginning 12 months prior to the application deadline and ending with the execution of the CY 2021 Allocation Agreement, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee's ability to issue QEIs to investors, or to terminate and rescind the NMTC Allocation made under this NOAA.

Furthermore, if prior to entering into an Allocation Agreement through this NOAA: (i) The CDFI Fund has made a final determination that an Affiliate of an Allocatee that is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund programs is in noncompliance of a previously executed assistance or award agreement or in default of a previously executed Allocation Agreement(s); (ii) the CDFI Fund has provided written notification of such determination to such organization; and (iii) the default occurs during the time period beginning 12 months prior to the application deadline and ending with the execution of the CY 2021 Allocation Agreement, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee's ability to issue QEIs to investors, or to terminate and rescind the NMTC Allocation made under this NOAA.

B. Allocation Agreement: Each Allocatee (including their Subsidiary Allocatees) must enter into an Allocation Agreement with the CDFI Fund. The Allocation Agreement will set forth certain required terms and conditions of the NMTC Allocation which may include, but are not limited to, the following: (i) The amount of the awarded NMTC Allocation; (ii) the approved uses of the awarded NMTC Allocation (*e.g.,* loans to or equity investments in QALICBs, loans to or equity investments in other CDEs); (iii) the approved service area(s) in which the proceeds of QEIs may be used, including the dollar amount of QLICIs that must be invested in Non-Metropolitan counties; (iv) commitments to specific innovative investments discussed by the Allocatee in its Allocation Application; (v) the time period by which the Allocatee may obtain QEIs from investors; (vi) reporting requirements for the Allocatee; and (vii) a requirement to maintain certification as a CDE throughout the term of the Allocation Agreement. If an Allocatee represented in its NMTC Allocation Application that it intends to invest substantially all of the proceeds from its investors in businesses in which persons unrelated to the Allocatee hold a majority equity interest, the Allocation Agreement will contain a covenant to that effect.

In addition to entering into an Allocation Agreement, each Allocatee must furnish to the CDFI Fund an opinion from its legal counsel or a similar certification, the content of which will be further specified in the Allocation Agreement, to include, among other matters, an opinion that an Allocatee (and its Subsidiary Allocatees, if any): (i) Is duly formed and in good standing in the jurisdiction in which it was formed and the jurisdiction(s) in which it operates; (ii) has the authority to enter into the Allocation Agreement and undertake the activities that are specified therein; (iii) has no pending or threatened litigation that would materially affect its ability to enter into and carry out the activities specified in the Allocation Agreement; and (iv) is not in default of its articles of incorporation, bylaws or other organizational documents, or any agreements with the Federal government.

If an Allocatee identifies Subsidiary Allocatees, the CDFI Fund reserves the right to require an Allocatee to provide supporting documentation evidencing that it Controls such entities prior to entering into an Allocation Agreement with the Allocatee and its Subsidiary Allocatees. The CDFI Fund reserves the right, in its sole discretion, to rescind its NMTC Allocation award if the Allocatee fails to return the Allocation Agreement, signed by the authorized representative of the Allocatee, and/or provide the CDFI Fund with any other requested documentation, including an approved legal opinion, within the deadlines set by the CDFI Fund.

C. Fees: The CDFI Fund reserves the right, in accordance with applicable Federal law and, if authorized, to charge allocation reservation and/or compliance monitoring fees to all entities receiving NMTC Allocations. Prior to imposing any such fee, the CDFI Fund will publish additional information concerning the nature and amount of the fee.

D. Reporting: The CDFI Fund will collect information, on at least an annual basis from all Allocatees and/or CDEs that are recipients of QLICIs, including such audited financial statements and opinions of counsel as the CDFI Fund deems necessary or desirable, in its sole discretion. The CDFI Fund will require the Allocatee to retain information as the CDFI Fund deems necessary or desirable and shall provide such information to the CDFI Fund when requested to monitor each Allocatee's compliance with the provisions of its Allocation Agreement and to assess the impact of the NMTC Program in Low-Income Communities.

The CDFI Fund may also provide such information to the IRS in a manner consistent with IRC § 6103 so that the IRS may determine, among other things, whether the Allocatee has used substantially all of the proceeds of each QEI raised through its NMTC Allocation to make QLICIs. The Allocation Agreement shall further describe the Allocatee's reporting requirements.

The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after due notice to Allocatees.

VII. Agency Contacts

The CDFI Fund will provide programmatic and information technology support related to the Allocation Application Mondays through Fridays, between the hours of 9:00 a.m. and 5:00 p.m. ET through the last day to contact the CDFI Fund. The CDFI Fund will not respond to phone calls or emails concerning the application that are received after the last day to contact the CDFI Fund. The CDFI Fund will respond to such phone calls or emails after the Allocation Application deadline in Table 1. Applications and other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's website at *https://www.cdfifund.gov.* The CDFI Fund will post on its website responses to questions of general applicability regarding the NMTC Program.

A. Information technology support: Technical support can be obtained by calling (202) 653–0422 or by submitting a Service Request in AMIS. People who have visual or mobility impairments that prevent them from accessing the Low-Income Community maps using the CDFI Fund's website should call (202) 653–0422 for assistance. These are not toll free numbers.

B. Programmatic support: If you have any questions about the programmatic requirements of this NOAA, contact the CDFI Fund's NMTC Program Manager by submitting a Service Request in AMIS; or by telephone at (202) 653–0421. These are not toll free numbers.

C. Administrative support: If you have any questions regarding the administrative requirements of this NOAA, contact the CDFI Fund's NMTC Program Manager by submitting a Service Request in AMIS, or by telephone at (202) 653–0421. These are not toll free numbers.

D. IRS support: For questions regarding the tax aspects of the NMTC Program, contact James Holmes and Dillon Taylor, Office of the Chief Counsel (Passthroughs and Special Industries), IRS, by telephone at (202) 317–4137, or by facsimile at (855) 591–7867. These are not toll free numbers. Applicants wishing for a formal ruling request should see IRS Internal Revenue Bulletin 2020–1, issued January 4, 2020.

VIII. Information Sessions

In connection with this NOAA, the CDFI Fund may conduct one or more information sessions that will be produced in Washington, DC and broadcast over the internet via webcasting as well as telephone conference calls. For further information on these upcoming information sessions, please visit the CDFI Fund's website at *https://www.cdfifund.gov.*

Authority: 26 U.S.C. 45D; 31 U.S.C. 321; 26 CFR 1.45D–1.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2021–24310 Filed 11–5–21; 8:45 am]

BILLING CODE 4810–05–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On October 28, 2021, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals:

1. SAYYED, Jamil (a.k.a. AL-SAYED, Jamil Muhammad Amin Amin (Arabic: جميل محمد امين السيد); a.k.a. EL SAYED, Jamil; a.k.a. EL SAYED, Jamil Mohamad Amin), Sea Road Summerland, Jnah, Beirut, Lebanon; Nabi Aylah, Zahleh, Bekaa, Lebanon; DOB 15 Jul 1950; POB Nabi Ayla, Beqaa, Lebanon; nationality Lebanon; Gender Male; Passport RL3234354 (Lebanon) expires 07 Jun 2020 (individual) [LEBANON].

   Designated pursuant to section 1(a)(i)(A) of Executive Order 13441 of August 1, 2007, "Blocking Property of Persons Undermining the Sovereignty of Lebanon or Its Democratic Processes and Institutions," 72 FR 43499, 3 CFR, 2008 Comp., p. 232 (E.O. 13441) for having taken, or posing a significant risk of taking, actions, including acts of violence, that have the purpose or effect of undermining Lebanon's democratic processes or institutions, or contributing to the breakdown of the rule of law in Lebanon.

2. KHOURY, Dany (Arabic: داني خوري), Lebanon; DOB 02 May 1967; POB Ramhala, Lebanon; nationality Lebanon; Gender Male; Passport LR0036899 (Lebanon) expires 17 Aug 2021 (individual) [LEBANON].

   Designated pursuant to section 1(a)(i)(A) of E.O. 13441 for having taken, or posing a significant risk of taking, actions, including acts of violence, that have the purpose or effect of undermining Lebanon's democratic processes or institutions, or contributing to the breakdown of the rule of law in Lebanon.

3. AL-ARAB, Jihad (Arabic: جهاد العرب) (a.k.a. EL ARAB, Jihad; a.k.a. EL ARAB, Jihad Ahmad), France Street Pavilion Building, Villa Jihad el Arab, Downtown Mina el Hosn, Beirut, Lebanon; DOB 06 Jan 1963; POB Beirut, Lebanon; nationality Lebanon; Gender Male; Passport LR0073000 (Lebanon) expires 25 Jul 2022 (individual) [LEBANON].

   Designated pursuant to section 1(a)(i)(A) of E.O. 13441 for having taken, or posing a significant risk of taking, actions, including acts of violence, that have the purpose or effect of undermining Lebanon's democratic processes or institutions, or contributing to the breakdown of the rule of law in Lebanon.

Dated: October 28, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021–24309 Filed 11–5–21; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8952

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Applications for Voluntary Classification Settlement Program.

DATES: Written comments should be received on or before January 7, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Applications for Voluntary Classification Settlement Program.

OMB Number: 1545–2215.

Form Number: 8952.

Abstract: Form 8952 was created by the IRS in conjunction with the development of a new program to permit taxpayers to voluntarily reclassify workers as employees for federal employment tax purposes and obtain similar relief to that obtained in the current Classification Settlement Program. To participate in the program, taxpayers must meet certain eligibility requirements, apply to participate in

VCSP, and enter into closing agreements with the IRS.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other-for-profit organizations.

Estimated Number of Respondents: 1,700.

Estimated Time per Respondent: 9 hours, 51 minutes.

Estimated Total Annual Burden Hours: 16,745.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 3, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–24340 Filed 11–5–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–S

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Proceeds From Real Estate Transactions.

DATES: Written comments should be received on or before January 7, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202)317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Proceeds From Real Estate Transactions.

OMB Number: 1545–0997.

Form Number: 1099–S.

Abstract: Internal Revenue Code section 6045(e) and the regulations there under require persons treated as real estate brokers to submit an information return to the IRS to report the gross proceeds from real estate transactions. Form 1099–S is used for this purpose. The IRS uses the information on the form to verify compliance with the reporting rules regarding real estate transactions.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other-for-profit organizations and individuals or households.

Estimated Number of Respondents: 2,573,400.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 411,744.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 3, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–24339 Filed 11–5–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Employer's Annual Tax Return for Agricultural Employees

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury 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. The public is invited to submit comments on these requests.

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

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–

8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Employer's Annual Tax Return for Agricultural Employees.

OMB Control Number: 1545–0035.

Type of Review: Reinstatement without change of a currently approved collection.

Description: Agricultural employers must prepare and file Form 943 and Form 943–PR (Puerto Rico only) to report and pay FICA taxes and income tax voluntarily withheld (Form 943 only). Agricultural employees may attach Forms 943–A and 943A–PR to Forms 943 and 943–PR to show their tax liabilities for semiweekly periods. The information is used to verify that the correct tax has been paid. Form 943 (Schedule R) allows (1) an agent appointed by an employer or payer or (2) a customer who enters into a contract that meets the requirements under 7705(e)(2) or (3) a client who enters into a service agreement described under Regulations section 31.3504–2(b)(2) with a Certified Professional Employer Organization, to allocate information reported on Form 943 to each client.

Form Numbers: IRS Form 943, IRS Form 943–PR, IRS Form 943–A, IRS Form 943A–PR, IRS Form 943X, IRS Form 943–X(PR), and IRS Form 943—Schedule R.

Affected Public: Businesses or other for-profit institutions.

Estimated Number of Respondents: 965,698.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 965,698.

Estimated Time per Response: 14 hours 1 minute.

Estimated Total Annual Burden Hours: 13,533,994 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 3, 2021.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2021–24379 Filed 11–5–21; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERAN AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veteran Affairs, Office of General Counsel.

ACTION: Notice of a modified system of records.

SUMMARY: VA is amending the current system of record (SOR) (173VA005OP2) the Department of Veterans Affairs (VA) Mobile Application Environment (MAE) by renaming it VA Enterprise Cloud—Mobile Application Platform (VAEC–MAP). The VA MAE has been replaced by VAEC–MAP. VA changed Information Technology providers from Terremark to Amazon Web Services (AWS). In addition, the system location has changed. We are restating the routine uses in full and revising the language to make routine uses align with recent Office of Management and Budget (OMB) guidelines and making minor editorial changes to more clearly articulate uses and to align with standardized VA routine use language. VA is republishing the system notice in its entirety. VAEC–MAP is a cloud hosted system that provides the infrastructure and hosting platform for Mobile Shared Services (*i.e.,* common services used for Mobile applications) and web components of applications used on Mobile devices. Mobile applications connect to VA enterprise services using the VAEC MAP Mobile Shared Services. Mobile applications such as Video Visits Service (VVS), Veteran Affairs Online Scheduling (VAOS), Patient Viewer (PV), and Veteran Affairs Video Connect (VVC) leverage this platform, pipeline, and hosting environment to provide a coordinated scheduling and notification capability to Staff and Veterans among other resources. VAEC–MAP uses the VAEC AWS cloud environment to provide an automated platform and pipeline for the development and hosting of production VA mobile applications. VAEC Common shared services, such as BigFix, Nessus, Splunk, and AD, are leveraged to provide security control implementation and system security visibility to the VA teams responsible for ensuring the security of VA systems. Administrative users of the VAEC–MAP environment must authenticate to the VA (Citrix Access Gateway or RESCUE) via Personal Identification Verification before using access keys and Identity and Access Management multi-factor authentication to gain access into the environment. System Administrators access the VA network using VA managed Government Furnished Equipment through Virtual Private Network connections to the VA Local Area Network and are authenticated using an Active Directory system managed by VA Network Security Operations Center. Encrypted communications protocols and ports are employed to protect information flowing across the VA network. All system access is managed via Role Based Access Control deployed separately within the environment and adheres to the Least Privilege Principal for all user accounts regardless of role. VAEC–MAP user account management adheres to VA policy or exceeds VA Policy where applicable.

DATES: Comments on this revision of a system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, these revisions will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005R1A), Washington, DC 20420. Comments should indicate that they are submitted in response to the VA Mobile Application Environment (MAE)-VA (173VA005OP2). Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: For submitting general questions and requests about this revised system please direct correspondence to Mark Ennis (System Owner) [Veteran Affairs 102 2nd Avenue South, Suite 300, St. Petersburg, FL 33701], or at *Mark.Ennis@va.gov,* and 727–212–0827 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA is amending the current system of record (SOR) (173VA005OP2) the Department of Veterans Affairs (VA) Mobile Application Environment (MAE) by renaming it VA Enterprise Cloud—Mobile Application Platform (VAEC–MAP) and updating the system location.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Dominic A. Cussatt, Acting Assistant Secretary of Information and Technology and Chief Information Officer, approved this document on May 26, 2021 for publication.

Dated: November 3, 2021.

Amy L. Rose,

Program Analyst, VA Privacy Service, Office of Information Security, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME AND NUMBER:

''VA Enterprise Cloud—Mobile Application Platform (Cloud) Assessing (VAEC–MAP) (173VA005OP2).

SECURITY CLASSIFICATION:

Sensitive But Unclassified (SBU).

SYSTEM LOCATION:

The office responsible for the system is the Department of Veteran Affairs, Office of General Counsel, 810 Vermont Ave. NW, Washington, DC 20420 and Amazon Web Services (AWS)—Seattle, WA.

SYSTEM MANAGER(S):

Mark Ennis (System Owner) Veteran Affairs 102 2nd Avenue South, Suite 300, St. Petersburg, FL 33701, or at *Mark.Ennis@va.gov,* and 727–212–0827 (This is not a toll-free number).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Section 501.

PURPOSE(S) OF THE SYSTEM:

The records and information will be used to provide a repository for the clinical and administrative information that is collected, retrieved, or displayed from within a VA mobile or Web application. The purpose of use will include, but not be limited to, health care treatment information, disability adjudication, and benefits to the Veteran both within the VA Medical Center and in sharing with partners who are participating through the eHealth Exchange in VA's Mobile pilots and subsequent public and enterprise rollout of new applications. Data may also be used at an aggregate, non-personally identifiable level to track and evaluate local or national health and benefits initiatives and preventative-care measures, such as detecting outbreaks of flu or other diseases, detection of antibiotic resistance bacteria, etc. These data may be used for such purposes as scheduling patient treatment services, including nursing care, clinic appointments, surveys, diagnostic, and therapeutic procedures. These data may also be used for the purpose of health care operations, such as producing various management and patient follow up reports; responding to patient and other inquiries; for epidemiological research and other health care-related studies; statistical analysis, resource allocation and planning; providing clinical and administrative support to patient medical care; determining entitlement and eligibility for VA benefits; processing and adjudicating benefit claims by Veterans Benefits Administration Regional Office staff; for audits, reviews, and investigations conducted by staff of VA Central Office and VA's OIG; sharing of health information between and among VHA, DoD, IHS, and other Government and private industry health care organizations; law enforcement investigations; quality assurance audits, reviews, and investigations; personnel management and evaluation; employee ratings and performance evaluations; and employee disciplinary or other adverse action, including discharge; advising health care professional licensing or monitoring bodies or similar entities of activities of VA and former VA health care personnel.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information on Veterans, Veteran beneficiaries, Veteran caregivers, members of the Armed Forces, Reserves and National Guard, and other VA customers in addition to VA authorized users (*e.g.,* VA employees, VA contractors, VA volunteers, and other individuals permitted to have access to VA IT systems).

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include information related to data entered through Web and mobile applications developed and maintained by VA, accessed and updated by the individuals covered by the system as well as by VA-authorized users. The records may contain demographics, personal information (*e.g.,* name, social security numbers, physical address, phone number, email address), health-related information (*e.g.,* vital signs, allergies, medications, health related history, health assessments), benefit-related information, information provided to VA for the potential provision of services and benefits, military history and services, preferences for authorizing the sharing of their health information (*e.g.,* electronic surrogate authorizations, electronic surrogate revocations). The records may include identifiers such as VA's integration control number. The information will be primarily benefits and health-related but may include other information such as customer entered updates to demographic information.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by Veterans and their beneficiaries or caregivers, members of the Armed Services, Reserves or National Guard; VA employees, other VA-authorized users (*e.g.,* DoD), and information from VA computer systems and databases include, but not limited to, Veterans Health Information Systems and Technology Architecture (VistA)—VA (79VA10P2) and National Patient Databases—VA (121VA10P2), VAMCs, Federal and non-Federal VLER/eHealth Exchange partners, and DoD.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. Congress

VA may disclose information to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. Data Breach Response and Remediation, for VA

VA may disclose information to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records,(2) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (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 VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm . . .

3. Data Breach Response and Remediation, for Another Federal Agency

VA may disclose information to another Federal agency or Federal entity, when VA determines that the 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.

4. Law Enforcement

VA may disclose information that, either alone or in conjunction with

other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, to a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing such law. The disclosure of the names and addresses of veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

5. DoJ for Litigation or Administrative Proceeding

VA may disclose information to the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her official capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components,

is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

6. Contractors

VA may disclose information to contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

7. OPM

VA may disclose information to the Office of Personnel Management (OPM) in connection with the application or effect of civil service laws, rules, regulations, or OPM guidelines in particular situations.

8. EEOC

VA may disclose information to the Equal Employment Opportunity Commission (EEOC) in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

9. FLRA

VA may disclose information to the Federal Labor Relations Authority (FLRA) in connection with: The investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised; matters before the Federal Service Impasses Panel; and the investigation of representation petitions and the conduct or supervision of representation elections.

10. MSPB

VA may disclose information to the Merit Systems Protection Board (MSPB) and the Office of the Special Counsel in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

11. NARA

VA may disclose information to NARA in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in the AWS Cloud.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name, social security number, VA's integration control number, or other assigned identifiers of the individuals for whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records from this system that are needed for audit purposes will be disposed of 6 years after a user's account becomes inactive. Routine records will be disposed of when the agency determines they are no longer needed for administrative, legal, audit, or other operational purposes. These retention and disposal statements are pursuant to NARA General Records Schedules GRS 20, item 1c and GRS 24, item 6a.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

1. Access to and use of national administrative databases, warehouses, and data marts are limited to those persons whose official duties require such access, and VA has established security procedures to ensure that access is appropriately limited. Information security officers and system data stewards review and authorize data access requests. VA regulates data access with security software that authenticates users and requires individually-unique codes and passwords. VA requires information security training for all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality. 2. Physical access to computer rooms housing national administrative databases, warehouses, and data marts is restricted to authorized staff and protected by a variety of security devices. Unauthorized employees, contractors, and other staff are not allowed in computer rooms. 3. Data transmissions between operational systems and national administrative databases, warehouses, and data marts maintained by this system of record are protected by state-of-the-art telecommunication software and hardware. This may include firewalls, intrusion detection devices, encryption, and other security measures necessary to safeguard data as it travels across the VA-Wide Area Network. 4. In most cases, copies of back-up computer files are maintained at off-site locations.

RECORD ACCESS PROCEDURES:

Individuals seeking information regarding access to and contesting of records in this system may write the Director of VA Connected Health, VHA Office of Informatics and Analytics, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Inquiries should, at a minimum, include the person's full name, social security number, type of information requested or contested, their return address, and phone number.

CONTESTING RECORD PROCEDURES:

Individuals seeking information regarding access to and contesting of records in this system may write the Director of VA Connected Health, VHA Office of Informatics and Analytics, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Inquiries should, at a minimum, include the person's full name, social security number, type of information requested or contested, their return address, and phone number.

NOTIFICATION PROCEDURES:

Individuals who wish to determine whether this system of records contains information about them should contact the Director of VA Connected Health, VHA Office of Informatics and Analytics, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or via the Web at *http://mobilehealth.va.gov.* Inquiries should include the person's full name,

social security number, and their return address.

EXEMPTIONS PROMULGATED FOR THE SYSTEM: N/A.

HISTORY: VA Mobile Application Environment (MAE)-VA (173VA005OP2) last full publication provided in 78 FR 66806 dated November 6, 2013

[FR Doc. 2021–24368 Filed 11–5–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0576]

Agency Information Collection Activity: Certification of Affirmation of Enrollment Agreement Correspondence Course

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VBA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed Reinstatement of a Previously Approved Information Collection and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 7, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0576'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0576'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3686(b); 38 U.S.C. 3323(a); 10 U.S.C. 16131, and 38 CFR 21.74256(b).

Title: Certification of Affirmation of Enrollment Agreement Correspondence Course.

OMB Control Number: 2900–0576.

Type of Review: Reinstatement of a previously approved collection.

Abstract: VA uses information from the current collection to pay education benefits for correspondence training. This information allows VA to determine if the claimant has been informed of the 5-day reflection period required by law.

Affected Public: Individuals and households.

Estimated Annual Burden: 3 hours.

Estimated Average Burden per Respondent: 3 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 69.

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. 2021–24346 Filed 11–5–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0613]

Agency Information Collection Activity: Record Keeping at Flight Schools

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration, Department of Veterans Affairs, is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed Reinstatement of a Previously Approved Information Collection and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 7, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0613'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0613'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the

burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3690(c); 38 CFR 21.4263(h)(3).

Title: Record Keeping at Flight Schools.

OMB Control Number: 2900–0613.

Type of Review: Reinstatement of a previously approved collection.

Abstract: The State approving agencies that approve courses for VA training use these records to determine if courses offered by flight schools should be approved. VA representatives use the records to determine the accuracy of payments made to VA students at flight schools.

Affected Public: Businesses or other for Profit or Not for Profit Schools.

Estimated Annual Burden: 557 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Annual.

Estimated Number of Respondents: 1,672.

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. 2021–24349 Filed 11–5–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Loan Guaranty: Maximum Allowable Fees for Legal Services

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: This notice provides updated information to participants in the Department of Veterans Affairs (VA) Home Loan Guaranty program concerning the maximum allowable fees for legal services performed in connection with the foreclosure of single-family housing loans. This notice also provides updated information concerning the legal fees for bankruptcy-related services. The table in this notice contains the amounts the Secretary has determined to be reasonable and customary in all states, following an annual review of the amounts allowed by other Government-related home loan programs.

DATES: The new maximum allowable fees for legal services will be allowed for all guaranty claims submitted to VA on or after December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Trevayne, Assistant Director for Loan and Property Management, Loan Guaranty Service (261), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632–8795. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The VA Home Loan Guaranty program authorized by title 38, United States Code, chapter 37, offers a partial guaranty against loss to lenders who make home loans to Veterans. VA regulations concerning the payment of loan guaranty claims are set forth at 38 CFR 36.4300, *et seq.* Computation of guaranty claims is addressed in 38 CFR 36.4324, which states that one part of the indebtedness upon which the guaranty percentage is applied is the ''[a]llowable expenses/advances as described in [38 CFR 36.4314].'' 38 CFR 36.4324(a)(2). Section 36.4314(b)(5)(ii) describes the procedures to be followed in determining what constitutes the reasonable and customary fees for legal services performed in connection with the foreclosure of single-family housing loans.

Pursuant to § 36.4314(b)(5)(ii), the Secretary is required to annually review allowances for legal fees in connection with the foreclosure of single-family housing loans, including bankruptcy-related services, issued by the Department of Housing and Urban Development (HUD), the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac). In March 2021, Fannie Mae issued revisions to their allowances for legal fees. Fannie Mae, *Allowable Foreclosure Attorney Fees Exhibit,* Servicing Guide (March 10, 2021), *https://servicing-guide.fanniemae.com.* The following month, HUD announced its plans to adopt Fannie Mae's fee structure by August. HUD, *National Servicing Center Single Family Housing Policy Handbook 4000.1 Section III: Servicing and Loss Mitigation Key Changes* (April 22, 2021), *https://www.hud.gov/sites/dfiles/SFH/documents/sfh_hb_4000_1_sect_3_serv_loss_mit_04_22_21.pdf.* Freddie Mac has also announced new allowances for legal fees, effective September 27, 2021. Freddie Mac, *Approved Attorney Fees and Title Expenses,* Seller/Servicer Guide Exhibit 57A (September 27, 2021), *https://guide.freddiemac.com/app/guide/exhibitRev/57A,09-27-2021.*

VA has reviewed and considered the legal fees allowed by each entity. Based on increases in fees for legal services announced by these Government-related home loan programs, the Secretary is publishing in the **Federal Register** a table setting forth the revised amounts the Secretary has determined to be reasonable and customary. The table reflects the primary method for foreclosing in each state, either judicial or non-judicial, with the exception of those states where either judicial or non-judicial is acceptable. The use of a method not authorized in the table will require prior approval from VA. This table will be available throughout the year at: *https://www.benefits.va.gov/HOMELOANS/servicers_valeri_rules.asp.*

There has been no change to the amounts VA will allow for bankruptcy filing fees. However, VA is clarifying that VA allows for a bankruptcy filing fee regardless of whether a bankruptcy release is obtained. VA notes that its current regulation at 38 CFR 36.4314(b)(5)(i) authorizes ''[f]ees for legal services actually performed.'' Regardless of whether a bankruptcy filing results in a release, legal services may have been performed in addressing the filing. Allowing fees for a bankruptcy filing is also consistent with the other Government-related home loan programs. See HUD, *National Servicing Center Single Family Housing Policy Handbook 4000.1 Section III: Servicing and Loss Mitigation Key Changes* (April 22, 2021), *https://www.hud.gov/sites/dfiles/SFH/documents/sfh_hb_4000_1_sect_3_serv_loss_mit_04_22_21.pdf.;* Fannie Mae, *Allowable Bankruptcy Attorney Fees Exhibit,* Servicing Guide (September 11, 2019), *https://servicing-guide.fanniemae.com;* Freddie Mac, *Approved Attorney Fees and Title Expenses,* Seller/Servicer Guide Exhibit 57A (September 27, 2021), *https://guide.freddiemac.com/app/guide/exhibitRev/57A,09-27-2021.* VA will continue to monitor fees for legal services on an annual basis and publish updates in the **Federal Register** as VA deems necessary.

The following table reflects the Secretary's determination of the reasonable and customary fees for legal services for the primary method for foreclosing in each state.

Jurisdiction	VA non-judicial foreclosure [1 2]	VA judicial foreclosure [1 2]	Deed-in-lieu of foreclosure
Alabama	$1,700	N/A	$400
Alaska	2,000	N/A	400
American Samoa	1,600	N/A	400
Arizona	1,700	N/A	400
Arkansas	1,700	N/A	400
California	1,700	N/A	400
Colorado	2,100	N/A	400
Connecticut	N/A	3,100	400
Delaware	N/A	2,250	400
District of Columbia	1,500	2,875	400
Florida	N/A	4,100	400
Georgia	1,700	N/A	400
Guam	2,000	N/A	400
Hawaii	N/A	4,500	400
Idaho	1,450	N/A	400
Illinois	N/A	3,000	400
Indiana	N/A	3,000	400
Iowa	1,275	2,450	400
Kansas	N/A	2,400	400
Kentucky	N/A	3,000	400
Louisiana	N/A	2,500	400
Maine	N/A	3,250	400
Maryland	3,000	N/A	400
Massachusetts	N/A	3,400	400
Michigan	1,900	N/A	400
Minnesota	1,775	N/A	400
Mississippi	1,500	N/A	400
Missouri	1,700	N/A	400
Montana	1,700	N/A	400
Nebraska	1,400	N/A	400
Nevada	2,000	N/A	400
New Hampshire	1,700	N/A	400
New Jersey	N/A	4,350	400
New Mexico	N/A	4,000	400
New York—Western Counties [3]	N/A	4,200	400
New York—Eastern Counties	N/A	5,225	400
North Carolina	2,175	N/A	400
North Dakota	N/A	2,200	400
Ohio	N/A	3,000	400
Oklahoma	N/A	2,700	400
Oregon	1,700	3,700	400
Pennsylvania	N/A	3,125	400
Puerto Rico	N/A	2,700	400
Rhode Island	2,250	N/A	400
South Carolina	N/A	2,850	400
South Dakota	N/A	2,250	400
Tennessee	1,500	N/A	400
Texas	1,700	N/A	400
Utah	1,700	N/A	400
Vermont	N/A	3,200	400
Virgin Islands	N/A	2,500	400
Virginia	1,700	N/A	400
Washington	1,700	N/A	400
West Virginia	1,450	N/A	400
Wisconsin	N/A	2,500	400
Wyoming	1,450	N/A	400

[1] When a foreclosure is stopped due to circumstances beyond the control of the holder or its attorney (including, but not limited to bankruptcy, VA-requested delay, property damage, hazardous conditions, condemnation, natural disaster, property seizure or relief under the Servicemembers Civil Relief Act) and then restarted, VA will allow a $400 restart fee in addition to the base foreclosure attorney fee. This fee recognizes the additional work required to resume the foreclosure action, while also accounting for the expectation that some work from the previous action may be utilized in starting the new action.

[2] VA will allow attorney fees of $1,050 (chapter 7) or $1,500 (initial chapter 13) for an initial bankruptcy filing, regardless of whether a bankruptcy release is obtained. For multiple bankruptcy filings under either chapter, VA will allow an additional $500.

[3] Western Counties of New York for VA are: Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Livingston, Monroe, Niagara, Ontario, Orleans, Steuben, Wayne, Wyoming and Yates. The remaining counties are in Eastern New York.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on November 1, 2021 and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2021–24330 Filed 11–5–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA), Veterans Benefits Administration.

ACTION: Notice of a modified system of records.

SUMMARY: As required by the Privacy Act of 1974, notice is hereby given that the Department of Veterans Affairs (VA) proposes to modify an existing system of records, ''Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records—VA'' (58VA21/22/28).

DATES: Comments on this modified system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005R1A), Washington, DC 20420. Comments should indicate that they are submitted in response to ''Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records—VA'' (58VA21/22/28). Comments received will be available at regulations.gov for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Michael F. Palmer, *Michael.Palmer5@va.gov,* Senior Program Analyst, Chief Production Office, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 (336) 251–0392.

SUPPLEMENTARY INFORMATION: This system of records contains information regarding applicants for and beneficiaries of benefits chiefly administered by the Veterans Benefits Administration (VBA). This system is a core system for VBA programs. This system of records does not directly address health or memorial benefits administered respectively by the Veterans Health Administration or the National Cemetery Administration, the other two of the three Administrations within VA. This system was first published on March 3, 1976, and last amended on February 14, 2019, to reaffirm the establishment of the Veterans Benefits Management System (VBMS) eFolder as the *official record* for Veterans claims processing, management, adjudication, and appeals, propose the plan to properly dispose of paper duplicate copies and other physical media after imaging and upload into the eFolder, and to begin using the eFolder as an integrated benefits repository for records related to VA Insurance and Loan Guarantee benefits.

VA is proposing to update this SORN to include the addition of two new applications that will be used by Vocational Rehabilitation and Employment (VR&E) counselors and/or Veteran participants: The Electronic Virtual Assistant (e-VA) and the Case Management Solution (CMS). e-VA is an active, artificial intelligence-enabled application that alleviates the burden of compliance, data entry, communications, documentation, and repetitive tasks in order to empower VR&E resources to focus their time on Veteran participants' needs, fulfilling the organization's mission of guiding clients to successful outcomes. e-VA's web-based capabilities allow for bi-directional automated and on-demand text and email communication between VA's VR&E counselors and Veterans who are seeking to use or are actively enrolled in VR&E programs. It provides program participants with the ability to submit documentation such as training certificates, training receipts, or employment verification documents using their mobile devices. It will also enable system-generated, interactive appointment scheduling, rescheduling and cancellation, plus keep Veterans updated by providing announcements and broadcast messages.

CMS is a Software as a Service application that will be used to automate the application process for VR&E, assign and transfer claimant files between VR&E counselors and stations, communicate with claimants, manage and record awards and payments to claimants, provide metrics on VR&E services, and ensure appropriate access controls are enabled for the system. CMS's web-based capabilities allow for bi-directional, automated, and on-demand integration between CMS and numerous VA systems, improving the automation, consistency and efficiency of VR&E counselors' work with claimants. It will also enable interaction with the e-VA system to ensure the value of both technologies is available to the VR&E counselors.

VA is also adding fiduciary records to this system as part of the retirement of legacy Beneficiary Fiduciary Field System (BFFS) that was covered under ''Supervised Fiduciary/Beneficiary and General Investigative Records—VA'' (37VA27). With the sunset of the BFFS system, Fiduciary records will be managed and stored in VBMS, which will serve as the primary application for the delivery of Fiduciary benefits to VA beneficiaries. In addition to the name, mailing address, Social Security number, medical record information, and financial information specific to VA Beneficiaries, VBMS will also store information on individuals/organizations serving as fiduciaries. This will include the name, mailing address, Social Security or tax identification number, and credit and criminal histories of individuals/organizations who are currently VA-appointed fiduciaries, who previously served as VA-appointed fiduciaries, or who were considered for service as VA-appointed fiduciaries. The purpose of maintaining these records is to qualify the individual/organization for service as a fiduciary and provide oversight of fiduciary activities. As such, additional Categories of Individuals, Categories of Records, Routine Uses, and other information specific to the VA Fiduciary program are being added to this system.

VA is also proposing to add the Filipino Loyalty File as a type of record stored in this system. The Filipino Loyalty File is a group of records relating generally to the loyalty of Filipino nationals during the Japanese occupation of the Philippine Islands during World War II (WWII). Most of the records were created or collected by Army investigative or intelligence units after the War and are used to help determine eligibility for VA benefits for Filipino nationals who served on behalf of the American cause during the War.

Additionally, VA is updating the name of the Virtual VA system to

Legacy Content Manager (LCM) due to its change in roles as a primary system used to process claims to a legacy system that is used to store documentation.

Finally, VA is adding new Routine Uses 84 to authorize VA to disclose information from this system of records to telephone company operators acting in a capacity to facilitate phone calls to or for hearing-impaired Veterans and their agents, and Routine Uses 85 to 93 to ensure better management and oversight of VA's Fiduciary program.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Neil C. Evans, M.D., Chief Officer, Connected Care, Performing the Delegable Duties of the Assistant Secretary for Information and Technology and Chief Information Officer, approved this document on September 26, 2021 for publication.

Dated: November 3, 2021.

Amy L. Rose,

Program Analyst, VA Privacy Service, Office of Information Security, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME AND NUMBER:

Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records—VA (58VA21/22/28).

SECURITY CLASSIFICATION:

This is an unclassified system.

SYSTEM LOCATION:

Records are maintained at VA regional offices, VA centers, the VA Records Management Center (RMC), St. Louis, Missouri, the Data Processing Center at Hines, Illinois, the Corporate Franchise Data Center in Austin, Texas, the VA Insurance Center and the Information Technology Center at Philadelphia, Pennsylvania, and Terremark Worldwide, Inc., Federal Hosting Facilities in Culpepper, Virginia, Miami, Florida, and in the VA Enterprise Cloud (VAEC) AWS GovCloud regions in Oregon and Ohio. Active educational assistance records are generally maintained at the regional processing office having jurisdiction over the educational institution, training establishment, or other entity where the claimant pursues or intends to pursue training.

The automated individual employee productivity records are temporarily maintained at the VA data processing facility serving the office in which the employee is located. Records provided to the Department of Housing and Urban Development (HUD) for inclusion on its Credit Alert Interactive Voice Response System (CAIVRS) are located at a data processing center under contract to HUD at Lanham, Maryland. Address locations of VA facilities are listed at: VA Locations Link.

SYSTEM MANAGER(S):

Executive Director, Compensation Service (21C), 810 Vermont Avenue NW, VA Central Office, Washington, DC 20420.

Executive Director, Pension and Fiduciary Service (21PF), 810 Vermont Avenue NW, VA Central Office, Washington, DC 20420.

Executive Director, Education Service (22), 810 Vermont Avenue NW, VA Central Office, Washington, DC 20420.

Executive Director, Veteran Readiness and Employment Service (28), 810 Vermont Avenue NW, VA Central Office, Washington, DC 20420.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 10 U.S.C. chapters 106a, 510, 1606 and 1607 and title 38, U.S.C. § 501(a) and Chapters 3, 11, 13, 15, 18, 19, 21, 23, 30, 31, 32, 33, 34, 35, 36, 37, 39, 51, 53, 55 and 77. Title 5 U.S.C. 5514.

PURPOSE(S) OF THE SYSTEM:

VA gathers or creates these records in order to enable it to administer statutory benefits programs to Veterans, Service Members, Reservists, and their spouses, surviving spouses, and dependents, who file claims for a wide variety of Federal Veteran's benefits administered by VA. See the statutory provisions cited in ''Authority for maintenance of the system.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The following categories of individuals are covered by this system.

1. Veterans who have applied for compensation for service-connected disability under title 38 U.S.C. chapter 11.
2. Veterans who have applied for nonservice-connected disability under title 38 U.S.C. chapter 15.
3. Veterans entitled to burial benefits under title 38 U.S.C. chapter 23.
4. Surviving spouses and children who have claimed pension based on nonservice-connected death of a Veteran under title 38 U.S.C. chapter 15.
5. Surviving spouses and children who have claimed death compensation based on service-connected death of a Veteran under title 38 U.S.C. chapter 11.
6. Surviving spouses and children who have claimed dependency and indemnity compensation for service-connected death of a Veteran under title 38 U.S.C. chapter 13.
7. Parents who have applied for death compensation based on service-connected death of a Veteran under title 38 U.S.C. chapter 11.
8. Parents who have applied for dependency and indemnity compensation for service-connected death of a Veteran under title 38 U.S.C. chapter 13.
9. Individuals who applied for educational assistance benefits administered by VA under title 38 U.S.C.
10. Individuals who applied for educational assistance benefits maintained by the Department of Defense (DoD) under title 10 U.S.C. that are administered by VA.
11. Veterans who apply for training and employers who apply for approval of their programs under the provisions of the Emergency Veterans' Job Training Act of 1983, Public Law 98–77.
12. Any VA employee who generates or finalizes adjudicative actions using the Benefits Delivery Network (BDN), the Veterans Service Network (VETSNET), CMS, or Veterans Benefits Management System (VBMS) computer processing systems.
13. Veterans who apply for training and employers who apply for approval of their programs under the provisions of the Service Members Occupational Conversion and Training Act of 1992, Public Law 102–484.
14. Representatives of individuals covered by the system.
15. Fee personnel who may be paid by the VA or by someone other than the VA (*e.g.,* appraisers, compliance inspectors, management brokers, loan closing and fee attorneys who are not VA employees but are paid for actual case work performed).
16. Program participants (*e.g.,* property management brokers and agents, real estate sales brokers and agents, participating lenders and their employees, title companies whose fees are paid by someone other than the VA, and manufactured home dealers, manufacturers, and manufactured home park or subdivision owners).
17. Disabled veterans who have applied for and received specially adapted housing assistance under title 38, U.S.C. chapter 21.
18. Veterans, their spouses or unmarried surviving spouses who have applied for and received VA housing credit assistance under title 38, U.S.C., chapter 37.

19. Person(s) applying to purchase VA owned properties (vendee loans).

20. Transferee owners of properties encumbered by a VA-guaranteed, insured, direct or vendee loan (*e.g.,* individuals who have assumed a VA-guaranteed loan and those who have purchased property directly from the VA).

21. Individuals other than those previously identified who may have applied for loan guarantee benefits.

22. Veterans (not including dependents) and members of the uniformed services (including dependents) who have applied for and/or have been issued government life insurance.

23. Beneficiaries of government life insurance entitled to or in receipt of insurance proceeds.

24. Attorneys drawing fees for aiding in settlement of VA insurance claims. The individuals noted above are covered by this system based on applications, claims, and notices of eligibility for the following government life insurance programs provided in title 38 U.S.C. chapters 19 and 21:

(1) U.S. Government Life Insurance (USGLI) under Section 1942.

(2) National Service Life Insurance (NSLI) under Section 1904.

(3) Veterans' Special Life Insurance (VSLI) under Section 1923.

(4) Veterans' Reopened Insurance (VRI) under Section 1925.

(5) Service-Disabled Veterans Insurance (S–DVI) under Section 1922 and 1922A.

(6) Veterans' Mortgage Life Insurance (VMLI) under Section 2106.

(7) Servicemembers' Group Life Insurance (SGLI), including Family Servicemembers' Group Life Insurance (FSGLI), Veterans' Group Life Insurance (VGLI), and Servicemembers' Group Life Insurance Traumatic Injury Protection.

(8) (TSGLI) under Sections 1967 through 1980A.

25. VA Fiduciary beneficiaries (*i.e.,* a veteran or a non-veteran adult who receives VA monetary benefits, lacks the mental capacity to manage his or her own financial affairs regarding disbursement of funds without limitation, and is either rated incapable of managing his or her financial affairs or adjudged to be under legal disability by a court of competent jurisdiction; or a child who has not reached majority under State law and receives VA monetary benefits).

26. Current, former, and prospective VA-appointed fiduciaries (*i.e.,* a VA Federal fiduciary appointed by VA to serve as fiduciary of VA monetary benefits for a VA beneficiary determined unable to manage his or her financial affairs; or a person or legal entity appointed by a State or foreign court to supervise the person and/or payee of a VA beneficiary adjudged to be under a legal disability). The statutory title of a court-appointed fiduciary may vary from State to State.

27. A chief officer of a hospital, domiciliary, institutional or nursing home care facility where a beneficiary, who VA has determined is unable to manage his or her financial affairs, is receiving care and who has contracted to use the veteran's VA funds in a specific manner.

28. Supervised Direct Payment (SDP) (*i.e.,* an adult beneficiary in the fiduciary program who manages his or her VA benefits with limited and temporary supervision based upon a field examination and subsequent to determination by the hub manager pertaining to benefits eligibility and other issues; or, to develop evidence for further investigations of potential criminal issues).

29. Physicians named in treatment records and financial managers or attorneys who help disperse funds for VA beneficiaries deemed unable to manage those funds.

CATEGORIES OF RECORDS IN THE SYSTEM:

The record, or information contained in the record, may include identifying information (*e.g.,* name, address, social security number); military service and active duty separation information (*e.g.,* name, service number, date of birth, rank, sex, total amount of active service, branch of service, character of service, pay grade, assigned separation reason, service period, whether Veteran was discharged with a disability, reenlisted, received a Purple Heart or other military decoration); payment information (*e.g.,* Veteran payee name, address, dollar amount of readjustment service pay, amount of disability or pension payments, number of nonpay days, any amount of indebtedness (accounts receivable) arising from title 38 U.S.C. benefits and which are owed to the VA); medical information (*e.g.,* medical and dental treatment in the Armed Forces including type of service-connected disability, medical facilities, or medical or dental treatment by VA health care personnel or received from private hospitals and health care personnel relating to a claim for VA disability benefits or medical or dental treatment); personal information (*e.g.,* marital status, name and address of dependents, internet protocol addresses, occupation, amount of education of a Veteran or a dependent, dependent's relationship to Veteran); education benefit information (*e.g.,* information arising from utilization of training benefits such as a Veteran trainee's induction, reentrance or dismissal from a program or progress and attendance in an education or training program); applications for compensation, pension, education and vocational rehabilitation benefits and training which may contain identifying information, military service and active duty separation information, payment information, medical and dental information, personal and education benefit information relating to a Veteran or beneficiary's incarceration in a penal institution (*e.g.,* name of incarcerated Veteran or beneficiary, claims file number, name and address of penal institution, date of commitment, type of offense, scheduled release date, Veteran's date of birth, beneficiary relationship to Veteran and whether Veteran or beneficiary is in a work release or half-way house program, on parole or has been released from incarceration); case notes from the e-VA application created from email and text message correspondence through the application; degree audits and copies of grades for Veterans and dependents enrolled in school; training records for Veterans and dependents participating in training programs. The Filipino Loyalty file (the File) consists of correspondence, memoranda, reports, affidavits, depositions, press clippings, rosters, photographs, and other papers accumulated by post-WWII U.S. Army investigative and intelligence units. The File relates to anti-Japanese resistance activities in the Philippines, Filipino collaboration with the Japanese, wartime guerrilla activities, and instances of real or suspected Communist activities.

The VA employee's BDN, VETSNET or VBMS identification numbers, the number and kind of actions generated and/or finalized by each such employee, the compilation of cases returned for each employee.

Records (or information contained in records) may also include: Applications for certificates of eligibility (these applications generally contain information from a veteran's military service records except for character of discharge); applications for Federal Housing Administration (FHA) Veterans' low-down payment loans (these applications generally contain information from a Veteran's military service records including whether or not a veteran is in the service); applications for a guaranteed or direct loan, applications for release of liability, applications for substitutions of VA entitlement and applications for specially adapted housing (these applications generally contain

information relating to employment, income, credit, personal data; *e.g.,* social security number, marital status, number and identity of dependents; assets and liabilities at financial institutions, profitability data concerning business of self-employed individuals, information relating to an individual Veteran's loan account and payment history on a VA-guaranteed, direct, or vendee loan on an acquired property, medical information when specially adapted housing is sought, and information regarding whether a Veteran owes a debt to the United States) and may be accompanied by other supporting documents which contain the above information; applications for the purchase of a VA acquired property (*e.g.,* vendee loans—these applications generally contain personal and business information on a prospective purchaser such as social security number, credit, income, employment history, payment history, business references, personal information and other financial obligations and may be accompanied by other supporting documents which contain the above information); loan instruments including deeds, notes, installment sales contracts, and mortgages; property management information; *e.g.,* condition and value of property, inspection reports, certificates of reasonable value, correspondence and other information regarding the condition of the property (occupied, vandalized), and a legal description of the property; information regarding VA loan servicing activities regarding default, repossession and foreclosure procedures, assumability of loans, payment of taxes and insurance, filing of judgments (liens) with State or local authorities and other related matters in connection with active and/or foreclosed loans; information regarding the status of a loan (*e.g.,* approved, pending or rejected by the VA); Applications by individuals to become VA-approved fee basis appraisers, compliance inspector, fee attorneys, or management brokers. These applications include information concerning applicant's name, address, business phone numbers, social security numbers or taxpayer identification number, and professional qualifications; applications by non-supervised lenders for approval to close guaranteed loans without the prior approval of VA (automatically); applications by lenders supervised by Federal or State agencies for designation as supervised automatic lenders in order that they may close loans without the prior approval (automatically) of the VA; applications for automatic approval or designation contain information concerning the corporate structure of the lender, professional qualifications of the lender's officers or employees, financial data such as profit and loss statements and balance sheets to insure the firm's financial integrity; identifying information such as names, business names (if applicable), addresses, phone numbers and professional resumes of corporate officials or employees; corporate structure information on prior approval lenders, participating real estate sales brokers or agents, developers, builders, investors, closing attorneys or other program participants as necessary to carry out the functions of the Loan Guaranty Program; records of performance concerning appraisers, compliance inspectors, management brokers, or fee attorneys on both firms and individual employees; records of performance including disciplinary proceedings, concerning program participants; *e.g.,* lenders, investors, real estate brokers, builders, fee appraisers, compliance inspectors and developers both as to the firm and to individual employees maintained on an as-needed basis to carry out the functions of the Loan Guaranty program; National Control Lists which identify suspended real estate brokers and agents, lenders and their employees, investors, manufactured home dealers and manufacturers, and builders or developers; and a master record of the National Control List (*e.g.,* Master Control List) which includes information regarding parties previously suspended but currently reinstated to participation in the Loan Guaranty program in addition to all parties currently suspended.

Life insurance records (or information contained in records) may consist of:

1. Applications for insurance, including the name and address of the Veteran or member of the uniformed services, email address, phone number, correspondence to and from the veteran or member of the uniformed services or their legal representatives, date of birth, social security number, military service number, dates of service, military ranking, character of discharge, VA file number, plan or type of insurance, disability rating, medical information regarding disability and health history, method of payment, amount of insurance coverage requested, and bank routing and account numbers. Applications for Veterans' Mortgage Life Insurance (VMLI), including supporting mortgage documents, contain the address of the mortgaged property, name and address of the mortgagor, the mortgage account number, the rate of interest, the original amount of the mortgage, and the current amount of the mortgage, the monthly payment amount, the mortgage payment period, and VA Specially Adapted Grant Cards (which contain the Veteran's or uniformed services member's name, address, dates of military service, branch of service, method of separation, whether the Veteran or member of the uniformed services has VMLI, the name and address of the lender, the legal description and property address, improvements to such property, date applied for disability compensation, date of initial application submission, grant information, amount of the grant approved or whether the grant was denied or canceled).

2. Beneficiary and option designation information, including the names and addresses of principal and contingent beneficiaries, beneficiary social security number, share amount to each beneficiary, the method of payment, and the designated estate(s) and trust(s).

3. Insurance contract information, including: (a) Authorization of allotment payment; (b) authorization for deduction from VA benefit payments; (c) authorization for deduction from military retired pay; (d) authorization for deduction from employee payroll; (e) paid dividend information; (f) claims for disability or death payments; (g) cash value, policy loan, and lien information; (h) a listing of lapsed actions and unpaid insurance proceeds; (i) payment vouchers; (j) reinstatement information; (k) premium records status, and retired status of the policy; (l) court-martial orders; (m) copies of personal papers of the insured, including birth certificate, marriage license, divorce decree, citizen or naturalization papers, death certificate, adoption decree, and family support documents; (n) correspondence to and from the Veteran, member of the uniformed services, legal representative and payee; (o) employment information; (p) returned check and check tracer information; (q) court documents; and (r) insurance death claims settlement information, including indebtedness, interest, and other credits.

4. Records of checks withheld from delivery to certain foreign countries.

5. Index of payees, including CO index cards and premium record cards.

6. Disability Outreach Tracking System (DOTS) records stored in the Veterans Insurance Claims Tracking and Response System (VICTARS) including the Veteran's or uniformed services member's name, address, phone number, and disability status.

7. Policy information and access history from the VA Insurance website self-service-portal stored in VICTARS, which includes the name of the insured,

file number, policy number, address, phone number, email address, loan status, including loan amount requested, denied, or pending, the date of request for information, loan history, policy changes, dividend option changes, and VA Insurance website pages accessed.

8. Information from the VA Insurance website, which provides access to Veterans for completion of an application for Service-Disabled Veterans Insurance (S–DVI), which includes the Veteran's name, address, social security number, date of birth, phone number, medical history, email address, and beneficiary information, such as the beneficiary's name, address, and social security number.

Fiduciary Records (or information contained in records) may consist of:

1. Field examination reports (*i.e.,* VA Form 27–4716a or 27–3190, Field Examination Request and Report, which contains a VA beneficiary's name, address, Social Security number, VA file number, an assessment of the beneficiary's ability to handle VA and non-VA funds, description of family relationships, economic and social adjustment information, information on the beneficiary's activities, and the name, address, and assessment of the performance of a VA-appointed fiduciary).

2. Correspondence from and to a VA beneficiary, a VA-appointed fiduciary, and other interested third parties.

3. Medical records (*i.e.,* medical and social work reports generated in VA, State, local, or private medical treatment facilities or private physicians' offices indicating the medical history of a VA beneficiary, including diagnosis, treatment and nature of any physical or mental disability).

4. Financial records (*e.g.,* accountings regarding a fiduciary's management of a beneficiary's income, investments, and accumulated funds, amount of monthly benefits received, amounts charged for fees by the fiduciary, certificates of balance on accounts from financial institutions, and withdrawal agreements between VA, financial institutions, and the fiduciary).

5. Court documents (*e.g.,* petitions, court orders).

6. Agreements to serve as a VA Federal fiduciary.

7. Information pertaining to individuals, including companies and other entities, who previously served as a VA-appointed fiduciary.

8. Information related to the qualification and appointment of individuals, including companies and other entities, considered by VA for appointment as a fiduciary.

9. Photographs of people (beneficiaries who VA has determined are unable to manage their financial affairs, fiduciaries, and other persons who are the subject of a VA investigation), places, and things.

10. Fingerprint records.

11. SSA records containing information about the type and amount of SSA benefits paid to beneficiaries who are eligible to receive benefits under both VA and SSA eligibility criteria, records containing information developed by SSA about SSA beneficiaries who are in need of representative payees, accountings provided to SSA, and records containing information about SSA representative payees. Also contained in this system are copies of non-fiduciary program investigation records. These records are reports of field examinations or investigations performed at the request of any organizational element of VA about any subject under the jurisdiction of VA other than a fiduciary issue. In addition to copies of the reports, records may include copies of exhibits or attachments such as photographs of people, places, and things; sworn statements; legal documents involving loan guaranty transactions, bankruptcy, and debts owed to VA; accident reports; birth, death, and divorce records; certification of search for vital statistics documents; beneficiary's financial statements and tax records; immigration information; and newspaper clippings.

RECORD SOURCE CATEGORIES:

Veterans, Servicemembers, Reservists, spouses, surviving spouses, dependents and other beneficiaries of the Veteran, accredited service organizations and other VA-approved representatives of the Veteran, VA-supervised fiduciaries (*e.g.,* VA Federal fiduciaries, court-appointed fiduciaries), military service departments, VA medical facilities and physicians, private medical facilities and physicians, education and rehabilitation training establishments, State and local agencies, other Federal agencies including the Department of Defense (DoD), Social Security Administration (SSA); U.S. Treasury Department, State, local, and county courts and clerks, Federal, State, and local penal institutions and correctional facilities, other third parties and other VA records, Office of Servicemembers' Group Life Insurance (OSGLI); commercial insurance companies; undertakers; lending institutions holding a veteran's or uniformed services member's mortgage; VA Loan Guaranty records; contractors remodeling or enlarging or adding construction to existing homes; relatives and other interested persons; Westlaw and InfoUSA; Inquiry Routing & Information System (IRIS) (maintained under System of Records ''151VA005OP6'' by the Office of Information &Technology), brokers and builder/sellers, credit and financial reporting agencies, an applicant's credit sources, depository institutions and employers, independent auditors and accountants, hazard insurance companies, taxing authorities, title companies, fee personnel, business and professional organizations, the general public, and other parties of interest involving VA-guaranteed, insured, vendee or direct loans or specially adapted housing; VA Fiduciary beneficiaries, VA beneficiaries' dependents, VA-appointed fiduciaries, individuals who were previously VA-appointed fiduciaries, individuals who VA considered for service as a VA-appointed fiduciary but did not select, field examiners, legal instrument examiners, fiduciary program personnel, third parties, other Federal, State, and local agencies, and VA records.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Note: To the extent that records contained in this system include individually-identifiable patient information protected by 38 U.S.C. 7332, that information cannot be disclosed under a routine use unless there is also specific disclosure authority in 38 U.S.C. 7332.

1. *Congress:* VA may disclose information to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. *Data breach response and remediation, for VA:* VA may disclose information to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records,· (2) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (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 VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

3. *Data breach response and remediation, for another Federal*

agency: VA may disclose information to another Federal agency or Federal entity, when VA determines that the information 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.

4. *Law Enforcement:* VA may disclose information that, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, to a Federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing such law. The disclosure of the names and addresses of Veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

5. *DOJ for Litigation or Administrative Proceeding:* VA may disclose information to the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her official capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components, is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

6. *Contractors:* VA may disclose information to contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

7. *Office of Personnel Management (OPM):* VA may disclose information to the Office of Personnel Management (OPM) in connection with the application or effect of civil service laws, rules, regulations, or OPM guidelines in particular situations.

8. *Equal Employment Opportunity Commission (EEOC):* VA may disclose information to the Equal Employment Opportunity Commission (EEOC) in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

9. *Federal Labor Relations Authority (FLRA):* VA may disclose information to the Federal Labor Relations Authority (FLRA) in connection with: The investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised; matters before the Federal Service Impasses Panel; and the investigation of representation petitions and the conduct or supervision of representation elections.

10. *Merit Systems Protection Board (MSPB):* VA may disclose information to the Merit Systems Protection Board (MSPB) and the Office of the Special Counsel in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

11. *National Archives and Records Administration (NARA):* VA may disclose information to NARA in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

12. *Governmental Agencies, for VA Hiring, Security Clearance, Contract, License, Grant:* VA may disclose information to a Federal, state, local, or other governmental agency maintaining civil or criminal violation records, or other pertinent information, such as employment history, background investigations, or personal or educational background, to obtain information relevant to VA's hiring, transfer, or retention of an employee, issuance of a security clearance, letting of a contract, or issuance of a license, grant, or other benefit. The disclosure of the names and addresses of veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

13. *State or Local Agencies, for Employment:* VA may disclose information to a state, local, or other governmental agency, upon its official request, as relevant and necessary to that agency's decision on the hiring, transfer, or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit by that agency. The disclosure of the names and addresses of veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

14. VA may disclose on its own initiative any information in this system, except the names and home addresses of individuals, that are relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statue or by regulation, rule or order issued pursuant thereto, to a Federal, State, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, rule, regulation or order.

15. VA may disclose on its own initiative the names and addresses of individuals, that are relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statue, regulation, rule or order.

16. The name and address of an individual, which is relevant to a suspected violation or reasonably imminent violation of law concerning public health or safety, whether civil, criminal or regulatory in nature an whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to any foreign, State or local governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that such name and address be provided for a purpose authorized by law.

17. The name, address, entitlement code (*e.g.,* compensation or pension), period(s) of service, sex, and date(s) of discharge may be disclosed to any nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under title 38 U.S.C. Disclosures may be in the form of a computerized list.

18. Any information in this system, except for the name and address of an individual, may be disclosed to a

Federal agency in order for VA to obtain information relevant to the issuance of a benefit under title 38 U.S.C. The name and address of an individual may be disclosed to a Federal agency under this routine use if they are required by the Federal agency to respond to the VA inquiry.)

19. Any information in this system may be disclosed in connection with any proceeding for the collection of an amount owed to the United States by virtue of a person's participation in any benefit program administered by VA when in the judgment of the Secretary, or official generally delegated such authority under standard agency delegation of authority rules (38 CFR 2.6), such disclosure is deemed necessary and proper, in accordance with title 38 U.S.C. 5701(b)(6).

20. *Consumer Reporting Agencies:* VA may disclose information as is reasonably necessary to identify such individual or concerning that individual's indebtedness to the United States by virtue of the person's participation in a benefits program administered by the Department, to a consumer reporting agency for the purpose of locating the individual, obtaining a consumer report to determine the ability of the individual to repay an indebtedness to the United States, or assisting in the collection of such indebtedness, provided that the provisions of 38 U.S.C. 57019(g)(2) and (4) have been met.

21. The name and address of an individual, and other information as is reasonably necessary to identify such individual, including personal information obtained from other Federal agencies through computer matching programs, and any information concerning the individual's indebtedness to the United States by virtue of the person's participation in a benefits program administered by VA, may be disclosed to a consumer reporting agency for purposes of assisting in the collection of such indebtedness, provided that the provisions of title 31 U.S.C. 3701–3702 and 3711–3718; and 38 U.S.C. 5701(g)(4) have been met.

22. Any information in this system, including available identifying information regarding the debtor, such as name of debtor, last known address of debtor, VA insurance number, VA loan number, VA claim number, place of birth, date of birth of debtor, name and address of debtor's employer or firm and dates of employment may be disclosed, under this routine use, except to consumer reporting agencies, to a third party in order to obtain current name, address, locator, and credit report in connection with any proceeding for the collection of an amount owed to the United States by virtue of a person's participation in any VA benefit program when in the judgment of the Secretary such disclosure is deemed necessary and proper. This purpose is consistent with the Federal Claims Collection Act of 1966 (Pub. L. 89–508, title 31 U.S.C. 951–953 and 4 CFR parts 101–105 and title 38 U.S.C. 5701(b)(6)).

23. Any information in this system, including the nature and amount of a financial obligation, may be disclosed to a debtor's employing agency or commanding officer so that the debtor-employee may be counseled by his or her Federal employer or commanding officer and to assist in the collection of unpaid financial obligations owed VA.

24. Payment information may be disclosed to the Department of the Treasury, in accordance with its official request, to permit delivery of benefit payments to Veterans or other beneficiaries.

25. Medical information may be disclosed in response to a request from the superintendent of a State hospital for psychotic patients, a commissioner or head of a State department of mental hygiene, or a head of a State, county or city health department or any fee basis physician or sharing institution in direct connection with authorized treatment for a Veteran, provided the name of the individual to whom the record pertains is given and the information will be treated as confidential, as is customary in civilian professional medical practice.

26. The name, address, VA file number, effective date of compensation or pension, current and historical benefit pay amounts for compensation or pension, service information, date of birth, competency payment status, incarceration status, and social security number of Veterans and their surviving spouses may be disclosed to the following agencies upon their official request: Department of Defense (DoD); Defense Manpower Data Center; Marine Corps; Department of Homeland Security; Coast Guard; Public Health Service; National Oceanic and Atmospheric Administration and Commissioned Officer Corps in order for these departments and agencies and VA to reconcile the amount and/or waiver of service, department and retired pay. These records may also be disclosed as a part of an ongoing computer-matching program to accomplish these purposes. This purpose is consistent with title 10 U.S.C. 12316, title 38 U.S.C. 5304 and title 38 U.S.C. 5701.

27. The amount of pension, compensation, dependency and indemnity compensation, educational assistance allowance, retirement pay and subsistence allowance of any individual identified to VA may be disclosed to any person who applies for such information as authorized by 38 U.S.C. 5701(c)(1).

28. Identifying, personal, payment and medical information may be disclosed to a Federal, State, or local government agency at the request of a Veteran in order to assist the Veteran and ensure that all of the title 38 U.S.C. or other benefits to which the Veteran is entitled are received. This information may also be disclosed upon the request from a Federal agency, or to a State or local agency, provided the name and address of the Veteran is given beforehand by the requesting agency, in order to assist the Veteran in obtaining a non-title 38 U.S.C. benefit to which the Veteran is entitled. These records may also be disclosed as part of an ongoing computer-matching program to accomplish this purpose.

29. Any information in this system, which directly affects payment or potential payment of benefits to contesting claimants, including parties claiming an apportioned share of benefits, may be coequally disclosed to each affected claimant upon request from that claimant in conjunction with the claim for benefits sought or received.

30. Any information in this system, such as identifying information, nature of a claim, amount of benefit payments, percentage of disability, income and medical expense information maintained by VA which is used to determine the amount payable to recipients of VA income-dependent benefits and personal information, may be disclosed to the Social Security Administration (SSA), upon its official request, in order for that agency to determine eligibility regarding amounts of social security benefits, or to verify other information with respect thereto. These records may also be disclosed as part of an ongoing computer-matching program to accomplish this purpose.

31. VA may disclose an individual's identifying information to an educational institution, training establishment, or other entity which administers programs approved for VA educational assistance in order to assist the individual in completing claims forms, to obtain information necessary to adjudicate the individual's claim, or to monitor the progress of the individual who is pursuing or intends to pursue training at the request of the appropriate institution, training establishment, or

other entity administrating approved VA educational programs or at the request of the Veteran.

32. *Researchers, for Research:* VA may disclose information from this system to epidemiological and other research facilities approved by the Under Secretary for Health for research purposes determined to be necessary and proper, provided that the names and addresses of veterans and their dependents will not be disclosed unless those names and addresses are first provided to VA by the facilities making the request.

33. VA may disclose information to a Federal agency for the purpose of conducting research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency.

34. *Claims Representatives:* VA may disclose information from this system of records relevant to a claim of a veteran or beneficiary, such as the name, address, the basis and nature of a claim, amount of benefit payment information, medical information, and military service and active duty separation information, at the request of the claimant to accredited service organizations, VA-approved claim agents, and attorneys acting under a declaration of representation, so that these individuals can aid claimants in the preparation, presentation, and prosecution of claims under the laws administered by VA.

35. Identifying and payment information may be disclosed, upon the request of a Federal agency, to a State or local government agency, to determine a beneficiary's eligibility under programs provided for under Federal legislation and for which the requesting Federal agency has responsibility. These records may also be disclosed as a part of an ongoing computer-matching program to accomplish these purposes. This purpose is consistent with title 38 U.S.C. 5701.

36. *Guardians, for Incompetent Veterans:* VA may disclose relevant information from this system of records in the course of presenting evidence to a court, magistrate, or administrative tribunal; in matters of guardianship, inquests, and commitments; to private attorneys representing veterans rated incompetent in conjunction with issuance of Certificates of Incompetency; and to probation and parole officers in connection with court-required duties.

37. *Guardians Ad Litem, for Representation:* VA may disclose information to a fiduciary or guardian ad litem in relation to his or her representation of a claimant in any legal proceeding as relevant and necessary to fulfill the duties of the fiduciary or guardian ad litem.

38. VA may disclose information to another federal agency, court, or party in litigation before a court or in an administrative proceeding conducted by a Federal agency, when the government is a party to the judicial or administrative proceeding.

39. Any information in this system including the name, social security number, date of birth, delimiting date and remaining entitlement of VA educational benefits, may be disclosed to the Department of Education (ED) upon its official request, or contractor thereof, for specific use by the ED to validate information regarding entitlement to VA benefits which is submitted by applicants who request educational assistance grants from the ED. The ED or contractor thereof will not use such information for any other purpose. These records may also be disclosed as part of an ongoing computer-matching program to accomplish this purpose.

40. VA may, at the request of the individual, disclose identifying information of an individual who is pursuing or intends to pursue training at an educational institution, training establishment, or other entity which administers programs approved for VA educational assistance in order for the VA to obtain sufficient information necessary to pay that individual or the educational or training establishment the correct monetary amounts in an expeditious manner. However, information will not be provided under this routine use to an educational institution, training establishment, or other entity when the request is clearly an attempt by that establishment to seek assistance in collection attempts against the individual.

41. Identifying information and information regarding the induction, reentrance and dismissal of a disabled Veteran from a vocational rehabilitation program may be disclosed at the request of the Veteran to a VA-approved vocational rehabilitation training establishment to ensure that the trainee receives the maximum benefit from training.

42. Identifying information and information regarding the extent and nature of a Veteran's disabilities with respect to any limitations to be imposed on the Veteran's vocational programs may be disclosed at the request of the Veteran to a VA-approved vocational rehabilitation training establishment to ensure that the trainee receives the maximum benefit from training.

43. Information regarding the type and amount of training/education received, and the name and address of a Veteran, may be disclosed at the request of a Veteran to local and State agencies and to prospective employers in order to assist the Veteran in obtaining employment or further training.

44. The name, claims file number and any other information relating to a Veteran's or beneficiary's incarceration in a penal institution and information regarding a dependent's right to a special apportionment of the incarcerated individual's VA benefit payment may be disclosed to those dependents who may be eligible for entitlement to such apportionment in accordance with title 38 U.S.C. 5313 and § 5307.

45. The name, claims file number and any other information relating to an individual who may be incarcerated in a penal institution may, pursuant to an arrangement, be disclosed to penal institutions or to correctional authorities in order to verify information concerning the individual's incarceration status. The disclosure of this information is necessary to determine that individual's continuing eligibility as authorized under title 38 U.S.C. 5313, § 5307. These records may also be disclosed as part of an ongoing computer-matching program to accomplish this purpose.

46. VA may disclose information from this system to other federal agencies for the purpose of conducting computer matches to obtain information to determine or verify eligibility of veterans receiving VA benefits or medical care under Title 38, U.S.C.

47. Identifying, disability, and award (type, amount and reasons for award) information may be released to the Department of Labor (DOL) in order for the DOL to conduct a computer matching program against the Office of Workers' Compensation Programs Federal Employees Compensation File, DOL/ESA–13, published in 46 FR 12357 on February 13, 1981. This match will permit the DOL to verify a person's eligibility for DOL payments as well as to detect situations where recipients may be erroneously receiving concurrent multiple payments from the DOL and VA, to identify areas where legislative and regulatory amendments directed toward preventing overpayments are needed, and to collect debts owed to the United States Government. This matching program is performed pursuant to the DOL Inspector General's authority under Public Law 95–452, section 4(a) to detect and prevent fraud and abuse.

This disclosure is consistent with title 38 U.S.C. 5701(b)(3).

48. Treasury, to Report Waived Debt as Income: VA may disclose information concerning an individual's indebtedness that is waived under 38 U.S.C. 3102, compromised under 4 CFR part 103, otherwise forgiven, or for which the applicable statute of limitations for enforcing collection has expired, to the Department of the Treasury as a report of income under 26 U.S.C. 61(a)(12).

49. Identifying information, including social security number, except for the name and address, may be disclosed to a Federal, State, County or Municipal agency for the purpose of conducting computer matches to obtain information to validate the entitlement of an individual, who is receiving or has received Veterans' benefits under title 10 or title 38 U.S.C. The name and address of individuals may also be disclosed to a Federal agency under this routine use if required by the Federal agency in order to provide information.

50. Identifying information, including the initials and abbreviated surname, the social security number, the date of birth and coding indicating the category of the individual's records, the degree of disability, the benefit program under which benefits are being paid and the computed amount of VA benefits for a calendar year may be released to the Department of the Treasury, and IRS, in order for IRS to conduct a computer matching program against IRS Forms 1040, Schedule R, Credit for the Elderly and the Permanently and Totally Disabled. This match will permit IRS to determine the eligibility for and the proper amount of Elderly and Disabled Credits claimed on IRS Form 1040, Schedule R. This matching program is performed pursuant to the provisions of Internal Revenue Code Section 7602. This disclosure is consistent with title 38 U.S.C. 5701(b)(3).

51. Identifying information, such as name, social security number, VA claim number, date and place of birth, etc., in this system may be disclosed to an employer or school having information relevant to a claim in order to obtain information from the employer or school to the extent necessary to determine that eligibility for VA compensation or pension benefits continues to exist or to verify that there has been an overpayment of VA compensation or pension benefits. Any information in this system also may be disclosed to any of the above-entitled individuals or entities as part of ongoing computer matching programs to accomplish these purposes.

52. *Treasury, for Withholding:* VA may disclose information concerning an individual's indebtedness by virtue of a person's participation in a benefits program administered by VA, to the Department of the Treasury for the collection of Title 38 benefit overpayments, overdue indebtedness, or costs of services provided to an individual not entitled to such services, by the withholding of all or a portion of the person's Federal income tax refund.

53. Veterans' addresses which are contained in this system of records may be disclosed to the Defense Manpower Data Center, upon its official request, for military recruiting command needs, DoD civilian personnel offices' mobilization studies and mobilization information, debt collection, and Individual Ready Reserve Units' locator services.

54. The name, address, VA file number, date of birth, date of death, social security number, and service information may be disclosed to the Defense Manpower Data Center. DoD will use this information to identify retired Veterans and dependent members of their families who have entitlement to DoD benefits but who are not identified in the Defense Enrollment Eligibility Reporting System program and to assist in determining eligibility for Civilian Health and Medical Program of the Uniformed Services benefits. This purpose is consistent with title 38 U.S.C. 5701. These records may also be disclosed as part of an ongoing computer-matching program to accomplish this purpose.

55. The name, address, VA file number, social security number, sex of Veteran, date(s) of birth of the Veteran and dependents, current benefit pay amounts for compensation or pension, pay status, check amount, aid and attendance status, Veteran and spouse annual income amounts and type and combined degree of disability will be disclosed to the Department of Health and Human Services. The SSA will use the data in the administration of the Supplemental Security Income payment system as prescribed by Public Law 92–603. These records may also be disclosed as part of an ongoing computer-matching program to accomplish these purposes. This purpose is consistent with title 38 U.S.C. 5701.

56. The names and current addresses of VA beneficiaries who are identified by finance centers of individual uniformed services of DoD and the Department of Homeland Security (Coast Guard) as responsible for the payment of Survivor Benefit Plan (SBP) premium payments to be released from this system of records to them upon their official written request for such information for their use in attempting to recover amounts owed for SBP premium payments.

57. This routine use authorizes VA to compile lists of the social security numbers and loan account numbers of all persons with VA-guaranteed and portfolio loans in default, or VA loans on which there has been a foreclosure and the Department paid a claim and provide these records to HUD for inclusion in its CAIVRS. Information included in this system may be disclosed to all participating agencies and lenders who participate in the agencies' programs to enable them to verify information provided by new loan applicants and evaluate the creditworthiness of applicants. These records may also be disclosed as part of an ongoing computer-matching program to accomplish these purposes.

58. SSA, HHS, for SSN Validation: VA may disclose information to the Social Security Administration and the Department of Health and Human Services for the purpose of conducting computer matches to obtain information to validate the social security numbers maintained in VA records.

This information may also be disclosed as part of a computer matching agreement to accomplish this purpose.

59. Any information contained in the files of Veterans whose claims were referred to VA Central Office for an advisory opinion concerning their claims that their disabilities were incurred secondary to occupational radiation exposure may be disclosed to the Department of the Navy. The information to be furnished to the Navy would include the medical opinions, dose estimates, advisory opinions, and rating decisions including Veterans' names, addresses, VA claim numbers, social security numbers and medical information. The requested information may be disclosed to the Department of the Navy upon receipt of its official written request for such information for its use in the review and assessment of its occupational radiation exposure controls and training.

60. A Veteran's claims file number and folder location may be disclosed to a court of proper jurisdiction that has issued a garnishment order for that Veteran under title 42 U.S.C. 659 through § 660. An individual's identifying and payment information may be disclosed to the educational institution, training establishment, or other entity the individual attends (or attended) if that individual received educational assistance from VA based on training at that educational institution, training establishment, or

entity. VA will disclose this information to assist the educational institution, training establishment, or other entity in verifying the individual's receipt of VA educational assistance and to assist the individual in applying for additional financial aid (*e.g.,* student loans).

61. The name and address of a prospective, present, or former accredited representative, claims agent or attorney and any information concerning such individual which is relevant to a refusal to grant access privileges to automated Veterans' claims records, or a potential or past suspension or termination of such access privileges may be disclosed to the entity employing the individual to represent Veterans on claims for Veterans benefits.

62. The name and address of a former accredited representative, claim agent or attorney, and any information concerning such individual, except a Veteran's name and home address, which is relevant to a revocation of such access privileges may be disclosed to an appropriate governmental licensing organization where VA determines that the individual's conduct that resulted in revocation merits reporting.

63. A record from this system (other than the address of the beneficiary) may be disclosed to a former representative of a beneficiary to the extent necessary to develop and adjudicate a claim for payment of attorney fees to such representative from past-due benefits under title 38 U.S.C. 5904(d) and Public Law 109–461 or to review a fee agreement between such representative and the beneficiary for reasonableness under title 38 U.S.C. 5904(c)(2) and Public Law 109–461.

64. Disclosure of tax returns and return information received from the IRS may be made only as provided by title 26 U.S.C. 6103 (an IRS confidentiality statute) also covering any IRS tax return information provided as part of an ongoing computer matching program.

65. Where VA determines that there is good cause to question the legality or ethical propriety of the conduct of a person or organization representing a person in a matter before VA, a record from this system may be disclosed, on VA's initiative, to any or all of the following: (1) Applicable civil or criminal law enforcement authorities and (2) a person or entity responsible for the licensing, supervision, or professional discipline of the person or organization acting as a representative. Name and home addresses of Veterans and their dependents will be released on VA's initiative under this routine use only to Federal entities.

66. The name and address of a beneficiary, and other information as is reasonably necessary to identify such a beneficiary, who has been adjudicated as incompetent under 38 CFR 3.353, may be provided to the Attorney General of the United States or his/her designee, for use by the DOJ in the National Instant Criminal Background Check System mandated by the Brady Handgun Violence Prevention Act, Public Law 103–159.

67. Disclosure may be made to the National Archives and Records Administration (NARA) and General Services Administration in record management inspections and such other activities conducted under Authority of title 44 U.S.C.

68. VA may disclose information from this system of records to the DOJ, either on VA's initiative or in response to DOJ's request for the information, after either VA or DOJ determines that such information is relevant to DOJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that release of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

69. Disclosure of relevant information may be made to individuals, organizations, public or private agencies, or other entities with whom VA has a contract or agreement or where there is a subcontract to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

70. Disclosure to other Federal agencies may be made to assist such agencies in preventing and detecting possible fraud, waste, overpayment, or abuse by individuals in their operations and programs as well as identifying areas where legislative and regulatory amendments directed toward preventing overpayments. These records may also be disclosed as part of an ongoing computer-matching program to accomplish this purpose.

71. VA may on its own initiative, disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) VA has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to the economic or property interests, identity theft or fraud, or harm to the programs (whether maintained by VA or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the VA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by VA to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in title 38 U.S.C. 5724, as the terms are defined in title 38 U.S.C. 5727.

72. VA may disclose information to other Federal Agencies including, but not limited to, identifying information, payment information, and vocational objectives about a Veteran or Servicemember who is receiving or has received benefits under the Vocational Rehabilitation program to be used in data analysis and development of performance measures.

73. Any information contained in this system may be disclosed by VA, as deemed necessary, to DoD for use for determinations required by DoD. VA will routinely use the information to conduct medical evaluations needed to produce VA disability ratings and to promulgate subsequent claims for benefits under title 38 U.S.C.

74. Information in this system (excluding date of birth, social security number, and address) relating to the use of transferred educational assistance benefits may be coequally disclosed to the transferor, *e.g.,* the individual from whom eligibility was derived, and to each transferee, *e.g.,* the individual receiving the transferred benefit. The information disclosed is limited to the two parties in each transferor-transferee relationship, as the transferor may have multiple transferred relationships.

75. The name, address, insurance account information of an insured Veteran or member of the uniformed services, their beneficiary(ies), legal representatives, or designated payee(s), and the amount of payment may be disclosed to the Treasury Department, upon its official request, in order for the

Treasury Department to make payment of dividends, policy loans, cash surrenders, maturing endowments, insurance refunds, issue checks and perform check tracer activities for the veteran or member of the uniformed services, beneficiary(ies), legal representative or designated payee(s).

76. The name and address of an insured Veteran or member of the uniformed services, date and amount of payments made to VA, including specific status of each policy (*e.g.,* premiums paid in, dividends paid out, cash and loan values) may be disclosed to the Internal Revenue Service (IRS), upon its official request, in order for the IRS to collect tax liens by withholding insurance payments to satisfy unpaid taxes. This purpose is consistent with title 26 of the United States Code, § 7602.

77. The name, address, social security number, date of discharge from the military, medical information concerning the grounds for total disability or the nature of an injury or illness, and dependency or beneficiary related information of a member of the uniformed services or Veteran may be disclosed to the Office of Servicemembers' Group Life Insurance (OSGLI) at the request of a member of the uniformed services or Veteran in order to aid OSGLI in the verification of such information for the purpose of issuance and maintenance of insurance policies provided to members of the uniformed services or Veterans participating in the Servicemembers' Group Life Insurance (SGLI) program and/or Veterans' Group Life Insurance (VGLI) program and to pay insurance benefits under these programs.

78. The name, address, and other identifying information such as a social security number or a military service number may be disclosed to the Department of Defense (Army, Air Force, Navy, Marine Corps); the Coast Guard of the Department of Homeland Security; the Commissioned Officers Corps of the U.S. Public Health Service; and the Commissioned Officers Corps of the National Oceanic and Atmospheric Administration (NOAA) of the Department of Commerce; this disclosure may be made upon their official request, for use in order for these departments to establish and maintain allotments from active and retired service pay for VA insurance premiums and loan repayments.

79. The face amount and cash and/or loan value of an insurance policy, verification of an existing insurance policy, and the name and address of an insured Veteran or member of the uniformed services may be disclosed at the request of the veteran or member of the uniformed services to a Federal, State, or local agency, in order for these agencies to assist a veteran or member of the uniformed services applying for Medicaid, Medicare, nursing home admittance, welfare benefits, or other benefits provided by the requesting agency to the extent that the information is relevant and necessary to the agency's decision regarding benefits.

80. The name and address of a Veteran or member of the uniformed services and military service information (*e.g.,* dates of service, branch of service) may be disclosed to the Armed Forces Institute of Pathology (AFIP), upon its official request, in order for the AFIP to conduct research for specified official purposes.

81. Any information in this system such as notice of renewal, reinstatement, premium due, lapse actions, miscellaneous insurance instructions, disposition of dividends, policy loans, and transfer of records may be disclosed to VA fiduciaries, court-appointed guardians/conservators, powers of attorney, or military trustees of incompetent Veterans or members of the uniformed services in order to advise VA fiduciaries, court-appointed guardians/conservators, powers of attorney, or military trustees of current actions to be taken in connection with ownership of U.S. government life insurance policies and to enable them to properly perform their duties as fiduciaries or guardians, powers of attorney, or military trustees.

82. Any information in this system of records may be disclosed, in the course of presenting evidence in or to a court, magistrate, administrative tribunal, or grand jury, including disclosures to opposing counsel in the course of such proceedings or in settlement negotiations.

83. Identifying information, except for the name and address of a Veteran or member of the uniformed services, may be disclosed to a Federal, State, County or Municipal agency for the purpose of conducting computer matches to obtain information to validate the entitlement of a Veteran or member of the uniformed services who is receiving or has received government insurance benefits under title 38 U.S.C. The name and address of a Veteran or member of the uniformed services may also be disclosed to a Federal agency under this routine use if they are required by the Federal agency to respond to the VA inquiry.

84. *Phone Operators, for the Hearing-Impaired:* VA may disclose information from this system of records to telephone company operators acting in a capacity to facilitate phone calls to or for hearing-impaired individuals, such as veterans or authorized agents, using telephone devices for the hearing-impaired, including Telecommunications Devices for the Deaf (TDD) or Text Telephones (TTY).

85. Any information in this system, including name, address, Social Security number, VA file number, medical records, financial records, and field examination reports of a VA beneficiary, and the name, address, and information regarding the activities of a VA-appointed fiduciary or beneficiary may be disclosed at the request of a VA beneficiary or fiduciary to a Federal, State, or local agency in order for VA to obtain information relevant to a VA decision concerning the payment and usage of funds payable by VA on behalf of a beneficiary, or to enable VA to assist a beneficiary or VA-appointed fiduciary in obtaining the maximum amount of benefits for a VA beneficiary from a Federal, State, or local agency.

86. Any information in this system, including name, address, Social Security number, VA file number, medical records, financial records, and field examination reports of a VA beneficiary who is in receipt of VA and SSA benefits concurrently, and the name, address, and information regarding the activities of a VA-supervised fiduciary may be disclosed to a representative of the SSA to the extent necessary for the operation of a VA program, or to the extent needed as indicated by such representative.

87. Any information in this system, including medical records, financial records, field examination reports, correspondence and court documents may be disclosed in the course of presenting evidence to a court, magistrate or administrative tribunal in matters of guardianship, inquests and commitments, and to probation and parole officers in connection with court required duties.

88. Any information in this system may be disclosed to a VA-appointed fiduciary in order for that fiduciary to perform his or her duties, provided this information will only be released when the disclosure is for the benefit of the beneficiary. Any information in this system may also be disclosed to a proposed fiduciary in order for the fiduciary to make an informed decision with regard to accepting fiduciary responsibility for a VA beneficiary.

89. Any information in this system, including medical records, correspondence records, financial records, field examination reports, and court documents may be disclosed to an attorney employed by the beneficiary, or

to a spouse, relative, next friend, or to a guardian ad litem representing the interests of the beneficiary, provided the name and address of the beneficiary is given beforehand and the disclosure is for the benefit of the beneficiary, and the release is authorized by 38 U.S.C. 7332, if applicable.

90. Any information in this system relating to the adjudication of a VA beneficiary's ability to manage his or her VA benefits, either by a court of competent jurisdiction or by VA, may be disclosed to a lender or prospective lender participating in the VA Loan Guaranty Program who is extending credit or proposing to extend credit on behalf of a veteran for VA to protect veterans in this category from entering into unsound financial transactions which might deplete the resources of the veteran and to protect the interest of the Government giving credit assistance to a Veteran.

91. The name and mailing address of a VA beneficiary, and other information as is reasonably necessary to identify such a beneficiary, who has been adjudicated as incapable of managing his or her financial affairs under 38 CFR 3.353, may be provided to the Attorney General of the United States or his/her designee, for use by DoJ in the National Instant Criminal Background Check System mandated by the Brady Handgun Violence Prevention Act, Public Law 103–59.

92. The name, mailing address, and any other information obtained by VA pertaining to the qualification of an individual seeking appointment as a VA fiduciary may be released to the beneficiary or his or her accredited representative or court-appointed guardian for the purpose of notifying the beneficiary of the reasons for selection or non-selection of the individual.

93. The name, mailing address, and any other information obtained by VA pertaining to the allegation, investigation, determination of misuse by a fiduciary, or determination of negligence on the part of VA may be released to the beneficiary or his or her accredited representative or court-appointed guardian for the purpose of notifying the beneficiary of the reasons for VA's decision regarding misuse.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The BDN, Legacy Content Manager (LCM), Corporate WINRS, VETSNET, The Image Management System (TIMS), Long Term Solution (LTS), CMS and the VBMS are data telecommunication terminal systems. For Compensation and Pension-related claims, records (or information contained in records) are no longer maintained on paper documents in claims folders (C-folders), but are now 100% digitized and stored in the VBMS electronic folder (VBMS eFolder). In 2012, VA declared the VBMS eFolder to be the *official record* for all documentation submitted to VA pursuant to claims for Compensation and Pension benefits. All paper documents VA receives pursuant to a Compensation or Pension claim are converted to a digital image via VA's electronic imaging process and uploaded into the VBMS eFolder. An electronically-imaged document in the VBMS eFolder is the *official copy of record* for adjudicating claims for VA Compensation or Pension benefits. When VA decision makers adjudicate claims for Compensation or Pension benefits, they rely solely on the electronic image contained in the VBMS eFolder, irrespective of whether a document is initially submitted to VA in electronic or paper format. VA decision makers do not have access to the original paper source documents during the claims adjudication process. Once a paper source document is electronically imaged and uploaded into the eFolder, VA considers the electronic image to be the *official copy of record,* while the physical paper document is reclassified as a *duplicate copy.* All *duplicate copies* of the official record are subject to destruction in accordance with applicable procedures and laws (please see the Retention and Disposal section for further details.)

VR&E and Education claims are maintained on paper, electronic folders, and on automated storage media (*e.g.,* microfilm, microfiche, magnetic tape and disks). Texts and emails from the Veterans pursuant to a VR&E claim are stored in the Corporate Database as a Corporate WINRS Case Note, which becomes the official record. Any texts and emails stored in the cloud/contractor server are considered duplicate copies. Such information may be accessed through BDN, VBMS, CMS, TIMS, LTS, and VETSNET terminals. BDN, LCM, Corporate WINRS, VETSNET, and VBMS terminal locations include VA Central Office, regional offices, VA health care facilities, Veterans Integrated Service Network offices, DoD Finance and Accounting Service Centers and the U.S. Coast Guard Pay and Personnel Center. Remote on-line access is also made available to authorized remote sites, representatives of claimants and to attorneys of record for claimants. A VA claimant must execute a prior written consent or a power of attorney authorizing access to his or her claims records before VA will allow the representative or attorney to have access to the claimant's automated claims records. Access by representatives and attorneys of record is to be used solely for the purpose of assisting an individual claimant whose records are accessed in a claim for benefits administered by VA. Information relating to receivable accounts owed to VA, designated the Centralized Accounts Receivable System (CARS), is maintained on magnetic tape, microfiche and microfilm. CARS is accessed through a data telecommunications terminal system at St. Paul, Minnesota.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

File folders, whether paper or electronic, are indexed by name of the individual and VA file number. Automated records are indexed by name, VA file number, payee name and type of benefit. Employee productivity is measured using automated systems. At the conclusion of a monthly reporting period, the generated listing is indexed by employee BDN identification number. Records in CAIVRS may only be retrieved by social security number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

All claims files folders for Compensation and Pension claims are electronically imaged and uploaded into the VBMS eFolder. Once a file is electronically imaged and established by VA as the official record, its paper contents (with the exception of documents that are on hold due to pending litigation, and service treatment records and other documents that are the property of DoD), are reclassified as *duplicate—non record keeping—copies* of the official record, and will be destroyed in accordance with Records Control Schedule VB–1, Part 1 Section XIII, Item 13–052.100 as authorized by NARA. All paper documentation that is not the property of VA (*e.g.,* DoD-owned documentation) is currently stored by VA after scanning, pending a policy determination as to its final disposition. All documentation being held pursuant to active litigation is held in its native format during the pendency of the litigation. All VBMS eFolders are stored on a secure VA server, pending permanent transfer to NARA where they will be maintained as historical records. Once an electronic record has been transferred into NARA custody, the record will be fully purged and deleted from the VA system in accordance with governing records control schedules

using commercial off the shelf (COTS) software designed for the purpose. Once purged, the record will be unavailable on the VA system, and will only be accessible through NARA.

Prior to destruction of any paper source documentation reclassified as *duplicate copies,* VA engages in a comprehensive and multi-layered quality control and validation program to ensure material that has been electronically imaged is completely and accurately uploaded into the VBMS eFolder. To guarantee the integrity and completeness of the record, VA engages in industry-best practices, using state-of-the-art equipment, random sampling, independent audit, and 100% VA review throughout the claims adjudication process. Historically, VA's success rate in ensuring the accuracy and completeness of the electronic record routinely and consistently exceeds 99%. Furthermore, no paper document is ever destroyed while any related claim or appeal for VA benefits is still pending. VA waits 3 years after the final adjudication of any claim or appeal before destroying the paper duplicate copies that have been scanned into the VBMS eFolder. As noted, the electronic image of the paper document is retained indefinitely as a permanent record either by VA or NARA.

Decisions to destroy VR&E paper counseling records are to be made in accordance with Records Control Schedule (RCS), RCS VB–1, Part I, Field in Section VII, dated January 31, 2014. Automated storage media containing temporary working information are retained until a claim is decided, and then destroyed. All other automated storage media are retained and disposed of in accordance with disposition authorization approved by NARA. Education file folders in paper are retained at the servicing Regional Processing Office. Education paper folders may be destroyed in accordance with the times set forth in the VBA Records Management, Records Control Schedule VB–1, Part 1, Section VII, as authorized by NARA.

Employee productivity records are maintained for two years after which they are destroyed by shredding or burning. File information for CAIVRS is provided to HUD by VA on magnetic tape. After information from the tapes has been read into the computer the tapes are returned to VA for updating. HUD does not keep separate copies of the tapes.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

1. Physical Security:

(a) Access to working spaces and claims folder file storage areas in VA regional offices and centers is restricted to VA employees on a need-to-know basis. Generally, file areas are locked after normal duty hours and the offices and centers are protected from outside access by the Federal Protective Service or other security personnel. Employee claims file records and claims file records of public figures are stored in separate locked files. Strict control measures are enforced to ensure that access to and disclosure from these claims file records are limited to a need-to-know basis. Duplicate paper copies after imaging are stored in NARA-compliant facilities, pending destruction.

(b) Access to BDN, LCM, Corporate WINRS, VETSNET, CMS, and VBMS data telecommunication networks are by authorization controlled by the site security officer who is responsible for authorizing access to the BDN, LCM, VBMS and VETSNET by a claimant's representative or attorney approved for access in accordance with VA regulations. The site security officer is responsible for ensuring that the hardware, software and security practices of a representative or attorney satisfy VA security requirements before granting access. The security requirements applicable to the access of automated claims files by VA employees also apply to the access of automated claims files by claimants' representatives or attorneys. The security officer is assigned responsibility for privacy-security measures, especially for review of violation logs, information logs and control of password distribution, including password distribution for claimants' representatives.

(c) Access to data processing centers is generally restricted to center employees, custodial personnel, Federal Protective Service and other security personnel. Access to computer rooms is restricted to authorized operational personnel through electronic locking devices. All other persons provided access to computer rooms are escorted.

(d) Employee production records are identified by the confidential BDN and VETSNET employee identification number, and are protected by management/supervisory personnel from unauthorized disclosure in the same manner as other confidential records maintained by supervisors.

2. BDN, LCM, VETSNET, CMS, e-VA, and VBMS System Security:

(a) Usage of the BDN, LCM, Corporate WINRS, VETSNET, e-VA and VBMS systems is protected by the usage of ''login'' identification passwords and authorized function passwords. The passwords are changed periodically. These same protections apply to remote access users.

(b) At the data processing centers, identification of magnetic tapes and disks containing data is rigidly enforced using labeling techniques. Automated storage media, which are not in use, are stored in tape libraries, which are secured in locked rooms. Access to programs is controlled at three levels: Programming, auditing and operations. Access to the data processing centers where HUD maintains CAIVRS is generally restricted to center employees and authorized subcontractors. Access to computer rooms is restricted to center employees and authorized operational personnel through electronic locking devices. All other persons granted access to computer rooms are escorted. Files in CAIVRS use social security numbers as identifiers. Access to information files is restricted to authorized employees of participating agencies and authorized employees of lenders who participate in the agencies' programs. Access is controlled by agency distribution of passwords. Information in the system may be accessed by use of a touch-tone telephone by authorized agency and lender employees on a ''need-to-know'' basis.

(3) e-VA and CMS System Security:

A unique SSL certificate has been generated for this connection which provides authentication for the e-VA and CMS applications, which enables an encrypted connection. Short Message Service (SMS) text messages are processed using a secure SMS gateway hosted by Twilio. The client's first and last name (the only PII in the text message) are encrypted when the information is passed back and forth. Emails are processed by AWS Simple Email Service (SES) using Transport Layer Security (TLS) protocol, which is a cryptographic protocol designed to provide communications security over a computer network. All emails to participants are sent from a single email address (*eva@eva.va.gov*).

RECORD ACCESS PROCEDURES:

Veterans and authorized parties have a statutory right to request a copy of or an amendment to a record in VA's possession at any time under the Freedom of Information Act (FOIA) and the Privacy Act (PA). VA has a decentralized system for fulfilling FOIA and PA requests. The type of information or records an individual is seeking will determine the location to which a request should be submitted. For records contained within a VA

claims folder (Compensation and Pension claims), or military service medical records in VA's possession, the request will be fulfilled by the VA Records Management Center. Authorized requestors should mail their Privacy Act or FOIA requests to: Department of Veterans Affairs, Claims Intake Center, P.O. Box 4444, Janesville, WI 53547–4444, DID: 608–373–6690.

For other benefits records maintained by VA (to include Vocational Rehabilitation & Employment, Insurance, Loan Guaranty or Education Service) submit requests to the FOIA/Privacy Act Officer at the VA Regional Office serving the individual's jurisdiction. Address locations for the nearest VA Regional Office are listed at VA Locations Link.

Any individuals who have questions about access to records may also call 1–800–327–1000. Information about how to contact Fiduciary services can be found here: *https://www.benefits.va.gov/FIDUCIARY/contact-us.asp.*

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

Any individual, who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such record, should submit a written request or apply in person to the nearest VA regional office or center. Address locations are listed at VA Locations Link.

VA employees wishing to inquire whether the system of records contains employee productivity information about themselves should contact their supervisor at the regional office or center of employment.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

There is no category of records in this system that has been identified as exempt from any section of the Privacy Act.

HISTORY:

Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records-VA (58VA21/22/28) was published on February 14, 2019 at 84FR4138.

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Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 512

[CMS–1749–F]

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Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2022. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this rule updates requirements for the ESRD Quality Incentive Program (QIP), including a measure suppression policy for the duration of the coronavirus disease 2019 (COVID–19) public health emergency (PHE) as well as suppression of individual ESRD QIP measures for Payment Year (PY) 2022 under the measure suppression policy. This rule also finalizes that CMS will not score facilities or reduce payment to any facility under the ESRD QIP in PY 2022. Further, this rule finalizes changes to the ESRD Treatment Choices (ETC) Model, which is a mandatory payment model that is focused on encouraging greater use of home dialysis and kidney transplants, to reduce Medicare expenditures while preserving or enhancing the quality of care furnished to Medicare beneficiaries.

DATES: These regulations are effective on January 1, 2022.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

ESRDApplications@cms.hhs.gov, for issues related to the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION: *Current Procedural Terminology (CPT) Copyright Notice:* Throughout this final rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

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I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates the ESRD PPS for CY 2022.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI payment rate for CY 2022.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This rule finalizes our proposals to suppress the use of certain ESRD QIP measure data for scoring and payment adjustment purposes in the PY 2022 ESRD QIP because we have determined that circumstances caused by the Public Health Emergency (PHE) for the coronavirus disease 2019 (COVID–19) pandemic have significantly affected the validity and reliability of the measures and resulting performance scores, as well as special scoring and payment policies for PY 2022. We are also finalizing our proposal to update the specifications for the SHR clinical measure beginning with the PY 2024 ESRD QIP. We are also finalizing our proposal to use CY 2019 data to calculate the PY 2024 ESRD QIP performance standards. This final rule further describes policies that will apply for PY 2025. Finally, this final rule describes several requests for information that also appeared in the CY 2022 ESRD PPS proposed rule. These requests for information solicited stakeholder feedback on several important topics, including strategies that we can use to address the gap in existing health inequities, the addition of COVID–19 vaccination measures in future rulemaking, and the use of digital quality measurement.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

This rule finalizes changes to the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC) Model, a mandatory Medicare payment model tested under the authority of section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model includes ESRD facilities and certain clinicians caring for beneficiaries with ESRD—or Managing Clinicians—located in Selected Geographic Areas as participants.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled, ''Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' The ETC Model is designed to test the effectiveness of adjusting certain Medicare payments to ETC Participants (ESRD facilities and Managing Clinicians—clinicians who furnish and bill the Monthly Capitation Payment (MCP) for managing ESRD Beneficiaries—who have been selected to participate in the ETC Model) to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. In the Specialty Care Models final rule, we established that the ETC Model adjusts payments for home dialysis and home dialysis-related claims with claim service dates from January 1, 2021 through December 31, 2023 through the Home Dialysis Payment Adjustment (HDPA). We are assessing the rates of home dialysis and of kidney transplant waitlisting and living donor transplantation, among beneficiaries attributed to ETC Participants during the period beginning January 1, 2021, and ending June 30, 2026. Based on those rates, we are applying the Performance Payment Adjustment (PPA) to claims for dialysis and dialysis-related services with claim service dates beginning July 1, 2022, and ending June 30, 2027. We codified these provisions in a new subpart of the Code of Federal Regulations (CFR) 42 CFR part 512, subpart C.

This final rule includes modifications to the ETC Model, including changes to the home dialysis rate and transplant rate, the PPA achievement benchmarking methodology, and the PPA improvement benchmarking and scoring methodology. We are also adding processes and requirements for ETC Participants to receive certain data from CMS and including certain additional waivers and flexibilities as part of the ETC Model test.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2022:* The final CY 2022 ESRD PPS base rate is $257.90. This amount reflects the application of the wage index budget-neutrality adjustment factor (0.99985) and a productivity-adjusted market basket increase of 1.9 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $257.90 (($253.13 × 0.99985) × 1.019 = $257.90).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2022, we are updating the wage index values based on the latest available data and continuing the 2-year transition to the Office of Management and Budget (OMB) delineations as described in the September 14, 2018 OMB Bulletin No. 18–04.
- *Update to the outlier policy:* We are updating the outlier policy using the most current data, as well as updating the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2022 using CY 2020 claims data. Based on the use of the latest available data, the final FDL amount for pediatric beneficiaries will decrease from $44.78 to $26.02, and the MAP amount will decrease from $30.88 to $27.15, as compared to CY 2021 values. For adult beneficiaries, the final FDL amount will decrease from $122.49 to $75.39, and the MAP amount will decrease from $50.92 to $42.75. The 1.0 percent target for outlier payments was not achieved in CY 2020. Outlier payments represented approximately 0.6 percent of total payments rather than 1.0 percent.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2022:* The

final CY 2022 average per treatment offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for capital-related assets that are home dialysis machines is $9.50. This offset amount reflects the application of the productivity-adjusted market basket increase of 1.9 percent ($9.32 × 1.019 = $9.50).

• *TPNIES applications received for CY 2022:* In this final rule, we announce our determination on the one TPNIES application under consideration for the TPNIES for CY 2022 payment.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2022. The final CY 2022 payment rate is $257.90, which is the same as the base rate finalized under the ESRD PPS for CY 2022.

3. ESRD QIP

We are adopting a measure suppression policy for the duration of the COVID–19 PHE that enables us to suppress the use of one or more measures in the ESRD QIP for scoring and payment adjustment purposes if we determine that circumstances caused by the COVID–19 PHE have significantly affected the measures and resulting performance scores. We are also finalizing our proposal to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, and the Long-Term Catheter Rate clinical measure for PY 2022 under the measure suppression policy. We are also finalizing our proposal to not score or reduce payment to any facility in PY 2022. We are finalizing our proposal to update the specifications for the SHR clinical measure beginning with the PY 2024 ESRD QIP. We are also finalizing our proposal for the PY 2024 ESRD QIP to use CY 2019 data to calculate the performance standards for that payment year. This final rule also announces the performance standards and estimated payment reductions that will apply for PY 2024. This final rule describes several policies continuing for PY 2025, but does not include any new requirements beginning with the PY 2025 ESRD QIP.

This final rule includes public comments received in response to requests for information that appeared in the CY 2022 ESRD PPS proposed rule. In those requests for information, we solicited stakeholder feedback on several important topics, including closing the gap in health equity, adding a COVID–19 vaccination measure for health care personnel (HCP) to the ESRD QIP measure set in future rulemaking, adding a COVID–19 vaccination measure for ESRD patients to the ESRD QIP measure set in future rulemaking, and potential actions and priority areas that would enable us to continue moving toward a greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR®) standard in quality measurement.

4. ETC Model

We are implementing the following changes to the ETC Model beginning for the third Measurement Year (MY3) of the Model, which begins January 1, 2022.

• *Beneficiary Attribution for Living Kidney Donor Transplants:* To better reflect the care relationship between beneficiaries who receive pre-emptive living donor transplants (LDT) and the Managing Clinicians who provide their care, we are modifying the methodology for attributing Pre-emptive LDT Beneficiaries to Managing Clinicians, such that a Pre-emptive LDT Beneficiary will be attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary during the 365 days prior to the transplant date.

• *Home Dialysis Rate Calculation:* To incentivize additional alternative renal replacement modalities under the ETC Model, we are adding nocturnal in-center dialysis to the calculation of the home dialysis rate for ESRD facilities and Managing Clinicians.

• *Transplant Rate Beneficiary Exclusion:* To better align with common reasons transplant centers do not place patients on the transplant waitlist, we are excluding beneficiaries with a diagnosis of, and who are receiving treatment with chemotherapy or radiation for, vital solid organ cancers from the calculation of the transplant rate.

• *Performance Payment Adjustment Achievement Benchmarking Methodology:* When we originally finalized the ETC Model, we stated our intent to increase achievement benchmarks above rates observed in Comparison Geographic Areas for future model years. As such, we will increase achievement benchmarks by 10 percent over rates observed in Comparison Geographic Areas every two MYs, beginning in MY3 (2022). We also will stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the Low Income Subsidy (LIS) during the MY, in recognition that beneficiaries with lower socioeconomic status have lower rates of home dialysis and transplant than those with higher socioeconomic status.

• *Performance Payment Adjustment Improvement Benchmarking and Scoring:* In conjunction with the stratification of the achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, we will introduce the Health Equity Incentive to the improvement scoring methodology used in calculating the PPA. CMS expects that the Health Equity Incentive will encourage ETC Participants to decrease disparities in renal replacement modality choice among beneficiaries with lower socioeconomic status by rewarding ETC Participants that demonstrate significant improvement in the home dialysis rate or transplant rate among their attributed beneficiaries who are dual-eligible or LIS recipients. We also will adjust the improvement scoring calculation to avoid the scenario where an ETC Participant cannot receive an improvement score because its home dialysis rate or transplant rate was zero during the Benchmark Year.

• *Performance Payment Adjustment Reports and Related Data Sharing:* To ensure that ETC Participants have timely access to ETC Model reports, we are establishing a process under which CMS will share certain model data with ETC Participants.

• *Medicare Waivers:* We are including an additional programmatic waiver to provide Managing Clinicians who are ETC Participants additional flexibility in furnishing the kidney disease patient education services described in § 410.48, namely a waiver of certain telehealth requirements as necessary solely for purposes of allowing ETC Participants to furnish kidney disease patient education services via telehealth under the ETC Model to take effect at the end of the COVID–19 PHE.

• *Kidney Disease Patient Education Services Coinsurance Waivers:* We will permit Managing Clinicians who are ETC Participants to reduce or waive the beneficiary coinsurance for kidney disease patient education services, subject to certain requirements. We have made the determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)), will be available to protect the reduction or elimination of coinsurance that is made in compliance with our policy.

C. Summary of Costs and Benefits

In section VIII.C.5 of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VIII.C.5.a of this final rule displays the estimated change in payments to ESRD facilities in CY 2022 compared to estimated payments in CY 2021. The overall impact of the CY 2022 changes is projected to be a 2.5 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.3 percent increase in payments compared with freestanding facilities with an estimated 2.5 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $290 million in CY 2022 compared to CY 2021. This reflects a $220 million increase from the payment rate update, a $70 million increase due to the updates to the outlier threshold amounts, and approximately $2.5 million in estimated TPNIES payment amounts, as further described in the next paragraph. Because of the projected 2.5 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.5 percent in CY 2022, which translates to approximately $60 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for new and innovative equipment and supplies, which is not budget neutral. As discussed in section II.C.1.a. of this final rule, we have determined that the Tablo® System, a hemodialysis machine that has FDA authorization for home use, has met the criteria for the TPNIES for CY 2022 payment. We estimate that the overall TPNIES payment amounts in CY 2022 would be approximately $2.5 million, of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.

2. Impacts of the Final Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VIII.C.5.b of this final rule displays the estimated change in payments to ESRD facilities in CY 2022 compared to estimated payments in CY 2021. The overall impact of the CY 2022 changes is projected to be a 1.9 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.0 percent increase in payments compared with freestanding ESRD facilities with an estimated 1.9 percent increase. The overall impact reflects the effects of the updated wage index and the final payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the final CY 2022 ESRD PPS base rate, will increase by $1 million in CY 2022 compared to CY 2021.

3. Impacts of the ESRD QIP

Our finalized policy to suppress measures for the PY 2022 ESRD QIP and to revise the scoring and payment methodology such that no facility will receive a payment reduction necessitated a modification to our previous estimated overall economic impact of the PY 2022 ESRD QIP (84 FR 60651). In the CY 2020 ESRD PPS final rule, we estimated that the overall economic impact of the PY 2022 ESRD QIP would be approximately $229 million as a result of the policies we had finalized at that time. The $229 million figure for PY 2022 included costs associated with the collection of information requirements, which we estimated would be approximately $211 million, and $18 million in estimated payment reductions across all facilities. However, as a result of the policies we are finalizing in this final rule for the PY 2022 ESRD QIP, we are modifying our previous estimate for PY 2022. We estimate that the new overall economic impact of the PY 2022 ESRD QIP will be approximately $215 million. The $215 million figure for PY 2022 only includes the costs associated with the collection of information requirements because there will be no payment reductions in PY 2022. We estimate that the overall economic impact of the PY 2024 ESRD QIP will be approximately $232 million, of which $215 million is associated with the collection of information requirements and $17 million is associated with the estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2025 ESRD QIP will be approximately $232 million.

4. Impacts of Changes to the ETC Model

The impact estimate in section VIII.B.4 of this final rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the changes in this final rule. We estimate that the ETC Model will result in $28 million in net savings over the 6.5-year duration of the ETC Model. We also estimate that $5 million of the estimated $28 million in net savings will be attributable to changes in this final rule.

II. Calendar Year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make

appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 22, or age 22–26) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) A training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a transitional drug add-on payment adjustment (TDAPA) for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 9, 2020, we published a final rule in the **Federal Register** titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program,'' referred to herein as the ''CY 2021 ESRD PPS final rule''. In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy, for CY 2021. We also finalized an update to the ESRD PPS wage index to adopt the 2018 OMB delineations with a transition period, changes to the eligibility criteria and determination process for the TPNIES, an expansion of the TPNIES to include certain new and innovative capital-related assets that are home dialysis machines, an addition to the ESRD PPS base rate to include calcimimetics in the ESRD PPS bundled payment, and a change to the low-volume payment adjustment eligibility criteria and attestation requirement to account for the coronavirus disease 2019 (COVID–19) Public Health Emergency (PHE). For further detailed information regarding these updates, see 85 FR 71398.

B. Provisions of the Proposed Rule, Public Comments, and Responses to the Comments on the CY 2022 ESRD PPS

The proposed rule, 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'' (86 FR 36322 through 36437), referred to as the ''CY 2022 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 9, 2021, with a comment period that ended on August 31, 2021. In that proposed rule, we proposed to make a number of annual updates for CY 2022, including updates to the ESRD PPS base rate, wage index, outlier policy, and the offset amount for TPNIES for capital-related assets that are home dialysis machines used in the home. The proposed rule presented a summary of the two CY 2022 TPNIES applications that we received by the February 1, 2021 deadline and our analysis of the applicants' claims related to substantial clinical improvement (SCI) and other eligibility criteria for the TPNIES.

We received 286 public comments on our proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and a dialysis coalition. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association, a professional association, and alliances for kidney care and home dialysis stakeholders; drug and device manufacturers; health care systems; a

health solutions company; and the Medicare Payment Advisory Commission (MedPAC).

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2022 ESRD PPS.

1. CY 2022 ESRD PPS Update

a. CY 2022 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 percent for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162). In the CY 2015 ESRD PPS final rule, we rebased and revised the ESRDB input price index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

We proposed to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2022 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI's) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets. Using this methodology and the IGI first quarter 2021 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2020), the proposed CY 2022 ESRDB market basket increase factor was 1.6 percent.

Under section 1881(b)(14)(F)(i) of the Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The productivity adjustment is calculated using a projection of multifactor productivity (MFP), which is derived by subtracting the contribution of labor and capital input growth from output growth. We finalized the detailed methodology for deriving the projection of MFP in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf.* We noted in the CY 2022 ESRD PPS proposed rule that for CY 2022 and beyond, we are changing the name of this adjustment to refer to it as the productivity adjustment, which is the term used in sections 1881(b)(14)(F)(i) and 1886(b)(3)(B)(xi)(II) of the Act, rather than the multifactor productivity or MFP adjustment. This is not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data. Using this methodology and the IGI first quarter 2021 forecast, the proposed productivity adjustment for CY 2022 (the 10-year moving average of MFP for the period ending CY 2022) was 0.6 percent.

As a result of these provisions, the proposed CY 2022 ESRD market basket increase factor reduced by the productivity adjustment was 1.0 percent. The proposed market basket increase factor is calculated by starting with the proposed CY 2022 ESRDB market basket percentage increase factor of 1.6 percent and reducing it by the proposed productivity adjustment (the 10-year moving average of MFP for the period ending CY 2022) of 0.6 percent.

As is our general practice, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the CY 2016-based ESRD market basket increase factor or productivity adjustment), we would use such data, if appropriate, to determine the final CY 2022 market basket update and productivity adjustment in this final rule (85 FR 36327).

We invited public comment on our proposals for the CY 2022 ESRD market basket update and productivity adjustment. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters encouraged CMS to examine the data sources and other elements to ensure that the market basket update reflects ESRD facilities' current experience. The commenters stated that while they understand CMS must follow the statutory framework for the annual market basket update, they believe that the proposed CY 2022 market basket update appears low given inflation and rising expenses including rent and labor. Several commenters expressed that they support the proposed ESRD PPS annual payment rate update for CY 2022 and support the use of more recent data for the market basket update and productivity adjustment, if available, to determine the final update factors for CY 2022. MedPAC commented that while it recognizes that CMS must provide the statutorily mandated payment update of the market basket minus the productivity adjustment, the Commission has concluded that this increase is not warranted based on their analysis of payment adequacy, which includes an assessment of beneficiary access, supply of ESRD facilities, and ESRD facilities' access to capital, quality, and financial indicators for the sector. MedPAC further recommended that Congress should eliminate the update to the ESRD PPS base rate for CY 2022.

Response: We acknowledge the concerns of some of the commenters and appreciate the support of some of the commenters regarding the proposed ESRD PPS annual payment rate update and use of more recent data to determine the market basket and productivity adjustment in determination of the final update factor. We also appreciate MedPAC's comments but note that the ESRD market basket increase factor is mandated by statute. For this final rule, we have incorporated more current historical data and revised forecasts provided by IGI that factor in expected price and wage pressures. By incorporating the most recent estimates available of the market basket update

and productivity adjustment, we believe these data reflect the best available projection of input price inflation faced by ESRD facilities for CY 2022, adjusted for economy-wide productivity, which is required by statute. As stated previously in this section of the final rule, consistent with our proposal to use more recent data, the CY 2022 ESRD market basket increase factor is 1.9 percent based on the more recent IGI third quarter 2021 forecast.

Comment: A few commenters noted that while they understand that the productivity adjustment is statutorily required, they believe that the experience of ESRD facilities argues against the idea that productivity can be improved year-over-year.

Response: We acknowledge the commenters' concerns regarding productivity growth at the economy-wide level and its application to ESRD facilities. As the commenter acknowledges, however, section 1881(b)(14)(F)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket increase factor for 2012 and subsequent years. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on ESRD provider margins as well as beneficiary access to care as reported by MedPAC.

Comment: One commenter recommended CMS replace the current price proxy for the non-Erythropoietin Stimulating Agents (ESA) Pharmaceutical cost weight in the 2016-based ESRD market basket Producer Price Index (PPI)—Commodity—Vitamin, nutrient, and hematinic preparations) with BLS PPI Commodity Data for Chemicals and Allied Products-Drugs and Pharmaceuticals, seasonally adjusted (BLS Series ID: WPS063 Series). The commenter further stated that they do not believe that the current proxy appropriately captures the price of drugs that fall within this category as they are not over-the-counter vitamins but prescription-only, synthesized hormones. The commenter also noted that there are new drugs under development currently that likely will be added to the ESRD PPS bundled payment during the next few years. The commenter asserted that an alternative proxy for the non-ESA drugs should be based on prescription drugs rather than the current proxy.

Response: We appreciate the commenter's suggestion and share the commenter's desire to use the most appropriate price proxy for non-ESA drugs in the ESRD market basket. As described in the CY 2019 ESRD PPS final rule (83 FR 56960 through 56961), and in the CY 2021 ESRD PPS final rule (85 FR 71428), we believe the PPI for Vitamins, Nutrients, and Hematinic Preparation (VNHP) is the most appropriate price proxy for non-ESA drugs and analysis of the Average Sales Price (ASP) data for Non-ESA drugs in the ESRD PPS bundled payment suggests the trends in the PPI VNHP trends are reasonable. We appreciate the commenter's concern about the potential shifts in the mix of drugs within the ESRD PPS bundled payment as new drugs enter the market. We will continue to monitor the impact that these changes have on the relative cost share weights and the mix of Non-ESA drugs included in the ESRD PPS bundled payment in the ESRDB market basket, and propose changes if appropriate in future rulemaking.

Final Rule Action: After considering the public comments, consistent with our historical practice and our proposal, we are estimating the market basket increase and the productivity adjustment based on IGI's forecast using the most recent available data. Based on IGI's third quarter 2021 forecast of the 2016-based ESRDB market basket with historical data through the second quarter of 2021, the 2016-based ESRDB market basket update for CY 2022 is 2.4 percent. IGI's 2021 third quarter forecast reflects a higher CY 2022 inflationary outlook compared to IGI's 2021 first quarter forecast, which is resulting in a notable upward revision to the CY 2022 ESRD market basket update for the CY 2022 ESRD PPS final rule (2.4 percent) compared to the CY 2022 ESRD PPS proposed rule (1.6 percent). As the economic impacts of the COVID–19 pandemic ease, the relatively higher inflation is resulting in relatively higher projected growth in wage, medical materials and supplies, and capital prices.

Based on the more recent data available from IGI's third quarter 2021 forecast, the current estimate of the productivity adjustment for CY 2022 (the 10-year moving average of MFP for the period ending CY 2021) is 0.5 percentage point. Therefore, the final CY 2022 ESRD market basket adjusted for the productivity adjustment is projected to be 1.9 percent (2.4 percent market basket update reduced by 0.5 percentage point productivity adjustment).

For the CY 2022 ESRD PPS payment update, we proposed to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56963). We invited public comment on the proposed labor-related share for CY 2022. We did not receive any comments on the proposal to continue using a labor-related share of 52.3 percent for CY 2022 and, therefore, are finalizing the continued use of a 52.3 percent labor-related share as proposed.

b. CY 2022 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use OMB's CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*.

For CY 2022, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize prefloor hospital data that are unadjusted for occupational mix. For CY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018 (fiscal year [FY] 2018 cost report data).

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable

proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

A wage index floor value (0.5000) is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In addition, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. Thus, for CY 2022, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

The comments received on the proposed CY 2022 ESRD PPS wage index and our responses to the comments are set forth below.

Comment: A coalition of dialysis organizations and a professional association acknowledged and supported the final phase-in of the updated OMB delineations for CY 2022. These commenters, along with another large dialysis organization, suggested that CMS consider ways to better tailor the ESRD PPS wage index, including using additional data beyond the hospital wage data. Another small dialysis organization expressed concerns that the ESRD PPS wage index does not keep pace with the hospital wage index, and identified several potential changes to align the ESRD PPS wage index with the hospital wage index, including the application of a statewide rural floor on wage indices, the application of different labor-related share percentages for areas with wage indices above and below 1, and allowing ESRD facilities to reclassify to a different geographic area. Another commenter, a non-profit kidney care alliance, expressed similar concerns and urged CMS to promptly address these disparities between the ESRD PPS wage index and the hospital wage index in rulemaking in the near future.

Response: We thank the commenters for their support, and we appreciate the suggestions for improving the ESRD PPS wage index. We did not propose changes to the ESRD PPS wage index methodology for CY 2022, and therefore we are not finalizing any changes to that methodology in this final rule. However, we will take these comments into consideration to potentially inform future rulemaking.

Comment: Three commenters, including a large dialysis organization, a non-profit health insurance organization in Puerto Rico, and a healthcare group in Puerto Rico, commented on the wage index for ESRD facilities located in Puerto Rico. These commenters recommended that CMS increase the wage index floor from 0.5000 to 0.5500; they noted that in the CY 2019 ESRD PPS proposed rule, CMS reported that its own analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. They noted that CMS further stated that any wage index values less than 0.5936 are considered outlier values. They pointed out that CMS still finalized a floor at 0.50 and characterized it as a balance between providing additional payments to affected areas while minimizing the impact on the ESRD PPS base rate. The commenters also recommended that CMS align the ESRD PPS wage index with the hospital wage index by applying to the ESRD PPS wage index the policy finalized in the FY 2020 IPPS final rule (84 FR 42326 through 42328) that increases the wage index for hospitals with a wage index value below the 25th percentile wage index. Two of the commenters further suggested that CMS conduct a survey of registered nurse (RN) and health worker wages specifically in standalone ESRD facilities in Puerto Rico as a means for wage index reform, noting that there is specific professional scope of practice standards for technicians in Puerto Rico outpatient facilities. Commenters asserted that RNs must provide all ESRD care in Puerto Rico outpatient facilities per local scope of practice laws, and that CMS should evaluate inpatient and outpatient facility data separately in order to get a fully accurate projection of wage costs for ESRD providers in Puerto Rico. Another commenter recommended that CMS evaluate policy inequities between the ESRD PPS wage index for ESRD facilities located in Puerto Rico compared to other states and territories, taking into consideration the unique circumstances that affect Puerto Rico, including its shortage of healthcare specialists and labor work force, remote geography, transportation and freighting costs, drug pricing, and lack of transitional care services.

Response: We thank the commenters for sharing their concerns regarding the ESRD PPS wage index for ESRD facilities in Puerto Rico and their suggestions for wage index reform. As noted in the CY 2018 ESRD PPS final rule (82 FR 50747) and the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we have received conflicting information from commenters about the local scope of practice for RNs and other staff impact on facility costs in Puerto Rico. Since we did not propose any changes to the wage index floor or wage index methodology for CY 2022, we are not finalizing any changes to those policies in this final rule. However, we appreciate the concerns that commenters have raised and we will take these thoughtful suggestions into account when considering future rulemaking.

Final Rule Action: We are finalizing the CY 2022 ESRD PPS wage indices based on the latest hospital wage data as proposed. For CY 2022, the labor-related share to which a facility's wage index is applied is 52.3 percent. As we finalized in the CY 2021 ESRD PPS final rule (85 FR 71436), there will be no cap applied to the reduction in the ESRD PPS wage index for CY 2022. The final CY 2022 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* Addendum A provides a crosswalk between the CY 2021 wage index and the CY 2022 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-*

Renal-Disease-ESRD-Payment-Regulations-and-Notices.

c. CY 2022 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis-stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as secondary hyperparathyroidism. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B ; (3) renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (4) renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (5) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were specified in Transmittal 2134, dated January 14, 2011.[1] Furthermore, CMS uses administrative issuances to update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these updates to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and items and services that have been incorrectly identified as eligible outlier services.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described in the following paragraphs) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

For CY 2022, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2020. As we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36329), we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available to best predict any future outlier payments; therefore, we proposed the outlier thresholds for CY 2022 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2020.

We also stated that we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. As discussed in section II.B.1.c of this final rule, CY 2020 claims data show outlier payments represent approximately 0.6 percent of total payments.

(1) CY 2022 Update to the Outlier Services MAP Amounts and FDL Amounts

For this final rule, the outlier services MAP amounts and FDL amounts were updated using 2020 claims data, as we proposed to do for CY 2022. The impact of this update is shown in Table 1, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2021 with the updated estimates for this final rule. The estimates for the CY 2022 outlier policy, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2022 prices for outlier services.

[1] Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

TABLE 1: Outlier Policy: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2021 (based on 2019 data, price inflated to 2021)*		Column II Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$30.33	$53.08	$25.91	$44.49
Adjustments				
Standardization for outlier services	1.0390	0.9789	1.0693	0.9805
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$30.88	$50.92	$27.15	$42.75
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$44.78	$122.49	$26.02	$75.39
Patient-month-facilities qualifying for outlier payment	8.80%	5.15%	12.89%	7.08%

*Note that Column I was obtained from Column II of Table 5 from the CY 2021 ESRD PPS final rule (85 FR 71437).

As demonstrated in Table 1, the estimated FDL amount per treatment that determines the CY 2022 outlier threshold amount for adults (Column II; $75.39) is lower than that used for the CY 2021 outlier policy (Column I; $122.49). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $50.92 to $42.75. For pediatric patients, there is a decrease in the FDL amount from $44.78 to $26.02. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $30.08 to $27.15.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2022 will be 7.08 percent for adult patients and 12.89 percent for pediatric patients, based on the 2020 claims data. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

(2) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2020 claims, outlier payments represented approximately 0.6 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. As we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36330), recalibration of the thresholds using 2020 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2022. We stated in the CY 2022 ESRD PPS proposed rule that we believe the update to the outlier MAP and FDL amounts for CY 2022 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us closer to meeting our 1 percent outlier policy goal, because we are using more current data for computing the MAP and FDL, which is more in line with current outlier services utilization rates. We noted in the CY 2022 ESRD PPS proposed rule that recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: Several commenters suggested alternatives to our proposed outlier MAP amounts, FDL amounts, and outlier percentage target for CY 2022. One large dialysis organization commented in support of using the most recent available CY 2020 claims data for determining the CY 2022 outlier services MAP amounts and FDL amounts, but suggested that CMS undertake further action to address the issue of outlier payments falling short of the 1 percent target. A professional organization of pediatric nephrologists expressed concern that the decreasing FDL and MAP amounts suggest that the cost of delivering pediatric ESRD care is not appropriately paid under Medicare by either the existing ESRD PPS bundled payment or through the outlier adjustment. Several commenters recommended that CMS set the CY 2022 outlier percentage less than 1 percent. For example, one commenter, a coalition of dialysis organizations, suggested that because the CY 2020 claims data showed that outlier payments represented approximately 0.6 percent of total ESRD PPS payments, CMS could set the CY 2022 outlier ''pool'' [percentage] at 0.6 percent. Similarly, a professional association suggested that because historical data shows that CMS regularly pays out between 0.5 and 0.6 percent of ESRD PPS payments as outlier payments, CMS should reduce the outlier percentage to better match the use of the outlier pool. Other commenters, including a large dialysis organization and a provider advocacy organization, urged CMS to reduce the CY 2022 outlier pool to no more than 0.5 percent of projected

aggregate ESRD PPS spending. Another large dialysis organization recommended CMS adopt the proposed FDL and MAP amounts for CY 2022, but urged CMS to set the outlier percentage to 0.6 percent.

Additionally, several of these commenters suggested that in any year when the outlier pool retains dollars that are not paid out, CMS should return those dollars to providers or reallocate those dollars to support reducing the barriers that create inequities in the care dialysis patients receive.

Response: We appreciate the support for the proposed use of CY 2020 data and the thoughtful suggestions provided by commenters. We acknowledge that, even with annually adjusting the MAP and FDL to reflect the most recent utilization and costs of ESRD PPS eligible outlier services, total outlier payments have not yet reached the 1 percent target. However, it is also true that use of eligible ESRD outlier services declined each year. That is, ESRD facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target. We also note that declining FDL and MAP amounts do not in themselves suggest that the ESRD PPS fails to adequately pay for the delivery of either pediatric or adult ESRD care. Rather, the ESRD PPS outlier policy was established to account for unusual variations in the type or amount of medically necessary care. Declining FDL and MAP amounts suggest that there is less costly variation in such care that is not included in the ESRD PPS bundled payment.

We appreciate the comments suggesting solutions for refining the outlier policy methodology, for example, reducing the outlier percentage withhold to less than 1 percent or establishing a mechanism that pays back ESRD facilities those allocated outlier amounts that did not pay out in the year projected. We did not propose any modifications to the ESRD PPS outlier policy for CY 2022, so we are not finalizing any changes to the methodology in this final rule. However, as discussed in section VI.E of the CY 2022 ESRD PPS proposed rule (86 FR 36400), CMS is considering potential revisions to the calculation of the outlier percentage to address stakeholder concerns, including concerns about the 1 percent outlier percentage, and issued a request for information in the CY 2022 ESRD PPS proposed rule to seek feedback on the acceptability of possible payment adjustment methods and to solicit information that would better inform future modifications to the methodology through rulemaking.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2022 displayed in Column II of Table 1 of this final rule and based on CY 2020 data.

d. Final Impacts to the CY 2022 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and calculating the per treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2022

We are finalizing an ESRD PPS base rate for CY 2022 of $257.90. This update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2022, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 2022 wage index budget-neutrality adjustment factor using treatment counts from the 2020 claims and facility-specific CY 2021 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2021. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2022. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD PPS wage index for CY 2022. As discussed in section II.B.1.b of this final rule, the ESRD PPS wage index for CY 2022 includes an update to the most recent hospital wage data, use of the 2018 OMB delineations, and no cap on wage index decreases applied for CY 2022. The total of these payments becomes the new CY 2022 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2022 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2022 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The CY 2022 wage index budget-neutrality adjustment factor is 0.99985. This application would yield a CY 2022 ESRD PPS base rate of $253.09 prior to the application of the market basket increase ($253.13 × 0.99985 = $253.09).

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2022 projection of the ESRDB market basket percentage increase factor is 2.4 percent. In CY 2022, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a of this final rule, the final productivity adjustment for CY 2021 is 0.5 percent, thus yielding an update to the base rate of 1.9 percent for CY 2022. Therefore, the final CY 2022 ESRD PPS proposed base rate is $257.90 ($253.02 × 1.019 = $257.90).

The comments and our responses to the comments on our updates to the CY 2022 ESRD PPS base rate are set forth below.

Comment: Several commenters raised concerns about the comorbidity case-mix adjustments under the ESRD PPS

and recommended eliminating them for CY 2022. Two commenters, including a large dialysis organization and a coalition of dialysis organizations encouraged CMS to eliminate the remaining comorbidity case-mix adjustments and thereby increase the ESRD PPS base rate for CY 2022. These commenters noted that the percent of claims with these conditions is relatively low and has been declining over time. These commenters argued that as the frequency of these conditions declines in the claims, maintaining these adjusters results in the loss of money from the system that could be redirected toward patient care. One of these commenters further argued that this means the dollars that Congress intended to go to providing items and services for individuals who receive dialysis are being inappropriately diverted away from that care. Both commenters further suggested that the years of discussion pertaining to patient-level adjustments, particularly the issues with the comorbid case-mix adjusters, and CMS's questions through the request for information (RFI) in the CY 2022 ESRD PPS proposed rule, should constitute enough notice to support their removal from the regression model for CY 2022, which includes the co-morbid case-mix adjusters in the calculation of the ESRD PPS payment.

Response: As the commenters noted, we included a detailed RFI regarding the ESRD PPS case mix adjustments in the CY 2022 ESRD PPS proposed rule (82 FR 36398 through 36409). A summary of the comments received in response to the RFI is provided in section VI.A of this final rule, and we will provide further information on the CMS ESRD PPS website in the future. CMS is considering alternative approaches to calculating the ESRD PPS case-mix adjustments that directly address stakeholder concerns, and appropriately reflect resource use and costs. The RFI in the CY 2022 ESRD PPS proposed rule both sought feedback on the variation of case-mix adjustments with duration of dialysis treatment, and solicited information on alternative proxies for resource utilization that can be reported at the patient/treatment level in order to better inform future modifications to this methodology through rulemaking.

With regard to the comment about removing the co-morbid adjustment from the case-mix for CY 2022, we note that due to the nature of regression analysis, which is how the current payment adjustors are set, making that type of adjustment would affect all the patient-level and facility-level adjustments. This can impact budget neutrality requirements and affect provider impacts differently than if adopted incrementally. Payment system changes can also require extensive efforts by CMS and providers to implement, and could not be implemented for CY 2022. While we discussed these case-mix adjustments in the RFI, we did not propose to make changes to the comorbidity case-mix adjustments for CY 2022; therefore, we are not finalizing any changes to that policy in this final rule.

Comment: Two commenters, a large dialysis organization and a non-profit health insurance organization in Puerto Rico, urged CMS to evaluate the accuracy of the ESRD PPS base rate as applied to payments for ESRD facilities located in Puerto Rico. These commenters encouraged CMS to consider the differences in patient characteristics between Puerto Rico and the mainland U.S., as well as differences in size, service capacity, and locality between the average ESRD facility in Puerto Rico versus other mainland providers.

Response: As mentioned previously in this section of the final rule, and as further discussed in section VI.D of the CY 2022 ESRD PPS proposed rule (86 FR 36399), CMS is considering alternative approaches to calculating the case-mix adjustment, including duration of dialysis treatment to allocate composite rate costs for patients with higher resource use due to patient characteristics as reflected in the case-mix adjustments. We are also considering all the commenters' suggestions in response to the RFI for alternative proxies for allocation of composite rate costs for those patients whose medical and physiologic characteristics require more resource use. We appreciate these comments and will take them into consideration to potentially inform future rulemaking.

Final Rule Action: We are finalizing a CY 2022 ESRD PPS base rate of $257.90. This amount reflects the CY 2022 wage index budget-neutrality adjustment factor of 0.99985, and the CY 2022 ESRD PPS productivity-adjusted market basket update of 1.9 percent.

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the basis of payment for the TPNIES for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this final rule, we will refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section § 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2-calendar years.

As we discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36331), the CY 2021 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.32. We stated that the proposed CY 2022 ESRD bundled market basket increase factor minus the productivity adjustment is 1.0 percent (1.6 percent minus 0.6 percent). Applying the proposed update factor of 1.010 to the proposed CY 2021 TPNIES offset amount resulted in a proposed CY 2022 TPNIES offset amount of $9.41 ($9.32 × 1.010). We proposed to update this calculation using the most recent data available in the CY 2022 ESRD PPS final rule.

The comments and our responses to the comments on the proposed update to the TPNIES offset amount are set forth below.

Comment: One large dialysis organization commented in support of the current TPNIES policy, but recommended that CMS recalculate the TPNIES offset amount using a 7-year depreciation schedule, which the commenter asserted would more accurately align with real-world home dialysis machine use. This commenter also recommended that CMS revise the TPNIES policy to allow for a modification to the ESRD PPS base rate to ensure ongoing access to innovative technologies.

Response: We appreciate the commenter's suggestion for improving

the TPNIES policy. As we discussed in the CY 2021 ESRD PPS final rule (85 FR 71421 through 71422), section 104.17 of the Provider Reimbursement Manual discusses that the useful life of a capital-related asset is its expected useful life to the provider, not necessarily the inherent useful or physical life. Further, the manual provides that under the Medicare program, only the American Hospital Association (AHA) guidelines may be used in selecting a proper useful life for computing depreciation. In keeping with the Medicare policy, we established reliance on the AHA guidelines to determine the useful life of a capital-related asset that is a home dialysis machine, which is 5-years and not the 7 years suggested by the commenter (see 42 CFR 413.236(f)(i)). We note that we considered alternatives, but concluded that this approach was simpler and appropriate for encouraging and supporting the uptake of new and innovative renal dialysis equipment and supplies (85 FR 71422).

We did not propose changes to the methodology for updating the TPNIES offset amount for CY 2022, and therefore we are not finalizing any changes to that methodology in this final rule. However, we will take these recommendations into consideration to potentially inform future rulemaking.

Final Rule Action: We are finalizing our proposal to calculate the CY 2022 TPNIES offset amount using the most recent data available. The CY 2021 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.32. As discussed previously in section II.B.1.a of this final rule, the CY 2022 ESRD bundled market basket increase factor minus the productivity adjustment is 1.9 percent (2.4 percent minus 0.5 percent). Applying the productivity adjustment factor of 1.019 to the CY 2021 TPNIES offset amount results in a CY 2022 TPNIES offset amount of $9.50 ($9.32 × 1.019).

f. TDAPA and TPNIES Public Comments and Responses

We also received several public comments on topics related to the TPNIES and the TDAPA policies under the ESRD PPS, including from individuals, such as ESRD beneficiaries, individual health care providers, manufacturers, healthcare groups, patient advocacy organizations, hospital associations, dialysis associations, as well as various dialysis, kidney, and professional organizations. While these comments related to issues that we either did not discuss in the CY 2022 ESRD PPS proposed rule or that we discussed for background or context, but for which we did not propose changes, a summary of the significant comments and our responses are set forth below.

Comment: Commenters overwhelmingly wrote in support of innovation in ESRD management generally and some specifically mentioned existing or upcoming technologies they thought would benefit ESRD patients. Other commenters expressed interest in seeing improvements in peritoneal dialysis, including on-line generation of dialysate and prevention of infections. Commenters also expressed support for home hemodialysis, citing its flexibility, convenience, and the comfort it provides patients. Commenters expressed interest in seeing improvements in home hemodialysis such as lower costs, more availability, better cannulation, reduced burden on patients and caregivers, and more convenient generation of dialysate. Commenters also stated they would like to see improvements in home dialysis that would increase retention, improve quality of delivered dialysate, or reduce complications.

Response: We appreciate the supportive comments regarding innovation in ESRD therapy. Like the commenters, CMS supports innovation in the ESRD space and we look forward to seeing new technologies that improve care for beneficiaries with ESRD.

Comments: Commenters provided input on the substantial clinical improvement criteria for the TPNIES under § 413.236(b)(5) and § 412.87(b)(1), offering specific recommendations on what CMS should consider in making a determination of substantial clinical improvement for the TPNIES. Commenters suggested that certain innovations could be considered evidence of substantial clinical improvement over existing technologies, such as: Technical specifications that make home dialysis easier for disadvantaged persons, real time dialysis fluid preparation, and real-time monitoring of patients' treatment sessions.

Many commenters encouraged CMS to utilize evidence outside of randomized controlled trials (RCTs) as a way of demonstrating significant clinical improvement due to the challenges of running clinical trials involving patients with ESRD, including difficulty in patient recruitment and financial barriers for innovators to conduct these types of large-scale, long-term trials. One commenter who agreed with this stated that CMS also should not only rely on short, small-scale studies conducted by device manufacturers as the standard for substantial clinical improvement. A home dialysis advocacy organization commented that evidence from a clinical trial, abstracts of data, and expert opinion, such as letters from medical professionals, are sufficient to support a showing of substantial clinical improvement, rather than RCTs. That same commenter added that given the challenges specific to conducting studies in the ESRD space, real-world evidence gathered from studies conducted outside the U.S. may be extrapolated to Medicare beneficiaries when appropriate. One commenter, a beneficiary, emphasized that patients may have a drastically different perspective of substantial clinical improvement compared to CMS. That commenter stated that greater flexibility is of the utmost importance to home dialysis patients and, therefore, therapies that allow patients with ESRD to resume their normal day-to-day activities should be considered to show substantial clinical improvement. Other commenters also encouraged the use of patient preferences, patient-reported outcomes, and other patient-centered data when evaluating substantial clinical improvement. A commenter encouraged CMS to weigh the reduction of patient and care partner burden, improved communication with the care team, and improved safety through the reduction of severe adverse events in the evaluation of evidence.

Other commenters offered suggestions for CMS's current process of evaluating evidence of substantial clinical improvement. Commenters asked that CMS provide guidance on evidence of substantial clinical improvement specific to the ESRD space, such as the development of a set of ESRD patient-reported outcomes for assessing substantial clinical improvement criteria. Other commenters also suggested using a panel of patients with ESRD to assist with tasks such as developing the set of patient-reported outcomes or providing insight for these outcomes during the evaluation process. Some commenters asked CMS to clarify how data and real-world evidence submitted as part of a TPNIES application is reviewed and weighed during the review process.

Response: We appreciate the comments regarding the CMS evaluation process for the substantial clinical improvement criterion for the TPNIES. In response to commenters' suggestions regarding the use of expert opinions, clinical trials, abstracts of data, unpublished sources, and letters from health care providers in our analysis, we note that under § 413.236(b)(5), CMS may consider all of these types of data,

among others, in making a determination of substantial clinical improvement. A list of information sources that we may consider in our determination is set forth in § 412.87(b)(1)(iii). Additionally, under § 412.87(b)(1)(iii)(N), CMS may consider other appropriate information sources not otherwise listed in our regulations on substantial clinical improvement. Further, we are taking the opportunity to clarify that RCTs, while potentially informative, are not required under existing regulations to demonstrate substantial clinical improvement for purpose of the TPNIES. While we did not propose changes to the substantial clinical improvement criteria for the TPNIES in the CY 2022 ESRD PPS proposed rule, we will consider these comments for future rulemaking. We encourage ESRD patients and patient advocacy organizations to submit comments on our annual ESRD PPS proposed rules to provide their perspectives on TPNIES applications.

Comment: Several commenters suggested changes to the TPNIES policy under the ESRD PPS. Commenters suggested using FDA determinations (for example, Breakthrough Device designations) in evaluating TPNIES applications. Commenters also asked for CMS to provide increased feedback to applicants throughout the TPNIES application process, including providing: Parallel feedback on data needed to support a TPNIES application as the manufacturers are working towards FDA marketing authorization, public review of the complete application prior to finalizing TPNIES application decisions, and an appeal process for manufacturers whose TPNIES applications were not approved. In addition, commenters recommended that CMS remove MACs' discretion in determining pricing of new and innovative renal dialysis equipment and supplies, as provided under § 413.236(e), and requested that CMS set more defined payment parameters and public transparency around pricing. Other commenters suggested expanding the TPNIES policy to allow TPNIES payments to ESRD facilities with home dialysis devices on operating leases and to expand the TPNIES eligibility to include all capital-related assets, not just home dialysis machines, as allowed under § 413.236(b)(6). We also received comments requesting various extensions to the TPNIES application deadlines and payment periods such as: Extending the duration of the TPNIES payment to 3 years, extending application timetables for device manufacturers applying for the TPNIES in the early years of the policy, and extending application timetables for manufacturers impacted by the COVID–19 PHE.

Response: We thank the public for their comments. Because we did not propose any changes to the TPNIES policy in the CY 2022 ESRD PPS proposed rule, we are not making any changes to that policy in this final rule; however, we will consider the commenters' recommendations for future rulemaking.

Comment: Several commenters also suggested changes to the TDAPA policy under § 413.234. For example, one commenter stated that CMS should consider implementing the substantial clinical improvement criteria used to evaluate the TPNIES applications for the TDAPA applications, and another commenter stated that CMS should not apply the TDAPA to biosimilar drugs.

Response: We thank the public for their comments. Because we did not propose any changes to the TDAPA policy in the CY 2022 ESRD PPS proposed rule, we are not making any changes to that policy in this final rule; however, we will consider the commenters' recommendations for future rulemaking.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2022 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, in order to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020; (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance, and (6) is not a capital related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we will use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal

dialysis service to make a diagnosis affects the management of the patient; or

- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the U.S. or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries. Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). Specifically, similar to the IPPS New Technology Add-On Payment, we wanted to align our goals with the agency's efforts to transform the healthcare delivery system for the ESRD beneficiary through competition and innovation to provide patients with better value and results. As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and outpatient settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we will announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular calendar year. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. We stated that the TPNIES is paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular calendar year to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the calendar year. In addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criterion, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS

rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID–19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. Per § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular calendar year, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular calendar year. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate. The CY 2021 TPNIES offset amount was $9.32. We finalized that this amount will be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171; (2) Is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) Has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the calendar year; (5) Is innovative, meaning it meets the criteria specified in § § 412.87(b)(1); and (6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

We received two applications for the TPNIES for CY 2022. One applicant, CloudCath (the applicant for the CloudCath Peritoneal Dialysis Drain Set Monitoring System), withdrew its application from consideration after the issuance of the CY 2022 ESRD PPS proposed rule because it did not receive FDA marketing authorization by July 6, 2021, which was the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services. Under § § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by the HCPCS Level II Code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. Therefore, the CloudCath Peritoneal Dialysis Drain Set Monitoring System is not eligible for consideration for the TPNIES for CY 2022. We are not including in this final rule the description and discussion of this application, which was included in the CY 2022 ESRD PPS proposed rule. We note that we received public comments on the application that was withdrawn. However, because the application was withdrawn and thus the technology is ineligible for the TPNIES for CY 2022, we are not summarizing nor responding to public comments regarding the TPNIES criteria for this technology in this final rule. A discussion of the remaining application, which met this deadline, is presented in this final rule.

The application discussed in this final rule is for a technology commonly used for the treatment of ESRD: Hemodialysis (HD). A detailed definition for HD is included in Chapter 11, Section 10 of the Medicare Benefits Policy Manual (Pub. L. 100–02).[2] In brief, HD is a process that involves blood passing through an artificial kidney machine and the waste products diffusing across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body. HD is accomplished usually in 3 to 5 hour sessions, 3 times a week.

a. Tablo® System

Outset Medical, Inc. submitted an application for the TPNIES for the Tablo® System for CY 2022. According to the applicant, the technology is an HD machine that has been designed for patient-driven self-care and to minimize system training time. The applicant stated that the system is intended to substantially improve the treatment of people with ESRD by removing barriers to home dialysis. The applicant explained that the Tablo® System is comprised of (1) the Tablo® Console with integrated water purification, on-demand dialysate production, and a touchscreen interface; (2) a proprietary, disposable, single-use pre-strung cartridge; and (3) the Tablo® Connectivity and Data Ecosystem. Per the applicant, the system is built to function in a connected setting with cloud-based system monitoring, patient analytics and clinical recordkeeping.

The applicant stated that the Tablo® System's features combine to provide a significantly differentiated HD solution with many benefits. First, the applicant stated that the Tablo® System's touchscreen interface made it easy to learn and use, guiding users through treatment using step-by-step

[2] Medicare Benefits Policy Manual (Pub. L. 100–102), available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

instructions with simple words and animation. The applicant also stated that instructions include non-technical language and color-coded parts to enable easier training, faster set-up, and simpler management including clear alarm explanations and resolution instructions.

Second, the applicant stated that the Tablo® System can accommodate treatments at home, allowing for flexibility in treatment frequencies, durations, and flow rates. Per the applicant, the Tablo® System did not have a pre-configured dialyzer, which allows clinicians to use a broad range of dialyzer types and manufactures, allowing for greater customization of treatment for the patient. The applicant stated that this was an improvement over the incumbent home device, which requires a separate device component and complex process to switch to another dialyzer.

Third, the applicant stated that the Tablo® System is an all-in-one system with integrated water purification and on-demand dialysate production, eliminating the need for industrial water treatment rooms that are required to operate traditional HD machines. The applicant also stated that electronic data capture and automatic wireless transmission eliminate the need for manual record keeping by the patient, care partner, or nurse. Per the applicant, a single-use Tablo® Cartridge with pre-strung blood, saline, and infusion tubing and a series of sensor-receptors mounted to an organizer snaps into the system, minimizing difficult connections that require additional training. The applicant stated that automated features, including an integrated blood pressure monitor, air removal, priming, and blood return, minimize user errors, save time, and streamline the user experience.

Fourth, the applicant stated that the Tablo® System's two-way wireless connectivity and data analytics provide the ability to continuously activate new capabilities and enhancements through wireless software updates, while also enabling predictive preventative maintenance to maximize machine uptime.

The applicant stated that currently 88 percent of patients receive HD in a clinic 3 times per week, for 3.0 to 4.5 hours a day and fewer than 2 percent perform HD treatment at home.[3] The applicant stated that 25 to 36 percent of home HD patients return to in-center care within 1 year of initiating HD at home.[4] [5] Per the applicant, barriers to home dialysis adoption and retention have been well studied and include treatment burden for patients and care partner fatigue; technical challenges with operating a HD machine; space, home modifications, and supplies management; patients not wanting medical equipment in the home; and safety concerns.[6] [7]

The applicant stated that innovation in making home dialysis more accessible to patients has been lacking due to a lack of investment funding, limited incremental reimbursement for new technology, and a consolidated, price-sensitive dialysis provider market where the lack of market competition is costly and has been associated with increased hospitalizations in dialysis patients.[8] The applicant stated that the Tablo® System was designed to address many system-related barriers that result in patients deciding on in-center care and/or stopping home modalities due to the burden of self-managed therapy.

The applicant stated that while peritoneal dialysis (PD), like HD, removes excess fluid and waste from the body, it has a different mechanism of action and relies on the body's own membrane, the peritoneum, to act as the ''dialyzer''. Per the applicant, PD requires surgical placement of a catheter in the abdomen and utilizes a cleansing fluid, dialysate, that must be infused and dwell in the abdomen to remove waste products from the blood. The applicant stated that PD must be conducted daily to achieve adequate dialysis and can be conducted manually or via a cycler; while in contrast, HD directly cleanses the blood with the use of a HD machine, dialysate and a dialyzer, which acts as an artificial kidney in removing excess fluid and toxins. The applicant stated that HD also requires surgical placement of a dialysis access, which is usually in the form of a catheter or a more permanent arteriovenous fistula.[9]

The applicant asserted that PD is the dominant home therapy used around the world, but should not be solely relied upon to increase growth in home dialysis, as there are physiological contraindications.[10] The applicant also stated that there is recent evidence that post 90-day mortality is higher in PD patients than in HD patients. Per the applicant, multivariable risk–adjusted analyses demonstrated that the mortality hazard ratio of HD versus PD is 0.74 (95 percent confidence interval (CI), 0.68–0.80) in the 270 to 360-day period after starting dialysis.[11] The applicant stated that patients and clinicians should weigh the risks and benefits of both options and select the one that meets the individual patient's preferences, goals, values and physiology. Per the applicant, because PD relies on the patient's own membrane, physiologic changes can occur and result in patients who are unable to continue PD due to loss of the ability to achieve adequacy. The applicant stated that these home patients could consider home HD rather than a return to in-center and noted that the practice of transitioning from one home modality to another is acknowledged by experts to be underutilized and is particularly pronounced in the U.S., where the ratio of PD use to home HD is 6:1,[12] as compared to 4:1 in Canada.[13]

[3] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2*. Accessed on Jan. 21, 2021.

[4] Seshasai, R.K., et al. (2019). The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150, 2019. doi:10.1111/hdi.12713.

[5] Weinhandl, Eric D., Collins Allan, Incidence of Therapy Cessation among Home Hemodialysis Patients in the United States, Abstract presented, American Society of Nephrology Kidney Week 2016.

[6] Seshasai, R.K., et al (2019). The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150, 2019. doi:10.1111/hdi.12713.

[7] Chan, Christopher T. et al. (2018). Exploring Barriers and Potential Solutions in Home Dialysis: An NKF–KDOQI Conference Outcomes Report American Journal of Kidney Diseases, Volume 73, Issue 3, 363–371.

[8] Erickson, K.F., Zheng, Y., Ho, V., Winkelmayer, W.C., Bhattacharya, J., & Chertow, G.M. (2018). Market Competition and Health Outcomes in Hemodialysis. Health services research, 53(5), 3680–3703. *https://doi.org/10.1111/1475-6773.12835*.

[9] Blake, P.G., Quinn, R.R., & Oliver, M.J. (2013). Peritoneal dialysis and the process of modality selection. Peritoneal dialysis international: Journal of the International Society for Peritoneal Dialysis, 33(3), 233–241. *https://doi.org/10.3747/pdi.2012.00119*.

[10] Ibid.

[11] Mukhopadhyay, P., Woodside, K.J., Schaubel, D.E., Repeck, K., McCullough, K., Shahinian, V.B., . . . & Saran, R. (2020). Survival among incident peritoneal dialysis versus hemodialysis patients who initiate with an arteriovenous fistula. Kidney Medicine, 2(6), 732–741.

[12] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2*. Accessed on Jan 21, 2021.

[13] Canada Institute for Health Information (2020): Annual Statistics. Available at: *https://secure.cihi.ca/estore/productSeries.htm?locale=en&pc=PCC24&_ga=2.265337481.729263172.1612199530-510791291.1610562424*. Accessed on Jan. 31, 2021.

The applicant asserted that the Tablo® System presented a significant clinical improvement over NxStage® System One™ (NxStage®), the current standard of home HD care, with the goal of getting patients access to easier to use technology and increasing the number of patients who can do dialysis at home. Per the applicant, NxStage® is the only other mobile HD machine that is approved for home use.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

With respect to the first TPNIES eligibility criterion under § 413.236(b)(1), whether the item has been designated by CMS as a renal dialysis service under § 413.171, maintenance dialysis treatments and all associated services, including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time, were included in the composite rate for renal dialysis services as of December 31, 2010 (75 FR 49036). An in-home HD machine would be considered equipment essential for the provision of maintenance dialysis. We received no public comments on whether the Tablo® System meets this criterion. Based on its status as an in-home HD machine, we consider the Tablo® System to be a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion under § 413.236(b)(2), whether the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant indicated that the Tablo® System received FDA marketing authorization for home use on March 31, 2020.[14] We received no public comments on whether the Tablo® System meets the newness criterion. Based on the information provided by the applicant, we agree that the Tablo® System meets the newness criterion.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

With respect to the third eligibility criterion under § 413.236(b)(3), whether the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, applicant indicated that the Tablo® System became available for home use on April 1, 2020. We received no public comments on whether the Tablo® System meets the commercial availability criterion. Based on the information provided by the applicant, we agree that the Tablo® System meets the commercial availability criterion.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

The fourth TPNIES eligibility criterion, under § 413.236(b)(4), is whether the applicant has submitted a complete HCPCS Level II code application in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. The applicant indicated that it submitted a HCPCS Level II code application on July 6, 2021, which was same day as the deadline specified HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services specified in CMS guidance.[15] We received no public comments on whether the Tablo® System meets this criterion. Based on the information provided by the applicant, we agree the applicant has met the HCPCS Level II application criterion.

(5) Innovation Criterion (§§ 413.236(b)(5) and 412.87(b)(1))

With respect to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant claimed that the Tablo® System significantly improves clinical outcomes relative to the current standard of care for home HD services, which it identified as the incumbent NxStage® home dialysis machine. The applicant presented the following substantial clinical improvement claims: (1) Decreased treatment frequency with adequate dialysis clearance; (2) increased adherence to dialysis treatment and retention to home therapy; and (3) improved patient quality of life. The applicant supported these claims with the Tablo® System Investigational Device Exemption (IDE) Study [16] and secondary support from four papers [17] [18] [19] [20] and two posters.[21] [22] The applicant also provided comparison data from three studies directly related to the incumbent [23] [24] [25] and an additional study that, based on the timeframe of the study, likely involved participants undergoing treatment with NxStage® although the article does not directly reference the incumbent.[26]

We provided an overview of these ten sources in the CY 2022 ESRD PPS proposed rule (86 FR 36333 through 36343), followed by the applicant's summary of how the data support each claim of substantial clinical improvement.[27] We also included in the CY 2022 ESRD PPS proposed rule a discussion of how we were applying the requirements of § 413.236(b)(5) to our review of the application and a summary of our preliminary concerns.

[14] As we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36334), in reviewing the enclosure to which the March 31, 2020 FDA authorization letter refers, the applicant's Section 510(k) submission indicated that the Tablo® Cartridge was reviewed separately from the Tablo® System and has its own separate 510(k) clearance. We further stated that, in the CY 2021 ESRD PPS final rule, CMS determined that the cartridge did not meet the newness criterion for the TPNIES (85 FR 71464) and as such, the cartridge was not new.

[15] *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2020-HCPCS-Application-and-Instructions.pdf.*

[16] *Clinicaltrials.gov* website. *https://www.clinicaltrials.gov/ct2/show/NCT02460263.* Last Updated July 1, 2020. *https://www.clinicaltrials.gov/ProvidedDocs/63/NCT02460263/Prot_000.pdf.*

[17] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

[18] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[19] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[20] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[21] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[22] Chahal, Y., Plumb, T., Aragon M. (2020). Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial. Poster Presentation at National Kidney Foundation Spring Clinical Conference, March 2020.

[23] Kraus, M., et al, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[24] Finkelstein, F.O., et al. (2012). At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney international, 82(5), 561–569.

[25] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: A matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[26] Suri, R.S., Li, L., & Nesrallah, G.E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney international, 88(2), 360–368.

[27] 86 FR 36335–36342.

We stated that we did not include detailed summaries of the remaining supplemental content included with the application. Specifically, the applicant submitted numerous supplemental background materials related to the dialysis industry, reimbursement patterns, modalities, treatment frequencies, patient adherence, hospitalization rates, and quality of life. The applicant also submitted several letters of support for the Tablo® System; three from dialysis patients, three from nephrologists, and one from a dialysis clinic nurse. These letters emphasized benefits of the Tablo® System, including reduced frequency of dialysis treatment, improved home dialysis retention, reduced patient and caregiver burden, reduced patient fatigue, and improved patient quality of life.

(a) Applicant Substantial Clinical Improvement Sources

As we discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36335), the applicant's primary support for its three substantial clinical improvement claims came from a prospective, multicenter, open-label, non-randomized crossover study that compared in-center and in-home HD performance using the Tablo® System. Per the applicant, this study is referred to as the Tablo® System Investigational Device Exemption (IDE) Study and the original study protocol and amendments were approved by FDA and registered on *http://www.clinicaltrials.gov* as ID: NCT02460263. The applicant stated that of the 30 participants enrolled (17 White and 13 Black or African American), 28 (18 men and 10 women) completed the study. Thirteen of the participants had previous home HD experience with NxStage®, and the remainder had previously received conventional in-center HD care. The applicant also noted that the Tablo® System IDE study sample was comprised of a representative cohort of dialysis patients and reported that it was similar to the population studied for the IDE study for the incumbent NxStage®. As described in the study protocol, the primary and secondary efficacy endpoints were a standardized weekly Kt/V of greater than or equal to 2.1 and ultrafiltration (fluid removal) value as reported by the device within ten percent of the expected fluid removal based on the ultrafiltration prescription and the Tablo® System Console fluid removal algorithm, respectively.[28] We clarified in the CY 2022 ESRD PPS proposed rule that Kt/V is a value used to quantify dialysis treatment adequacy and ''K'' = dialyzer clearance, ''t'' = time, and ''V'' = Volume of distribution of urea. The applicant stated that each study participant served as his or her own control and remained in the trial for approximately 21 weeks, during which time they were prescribed HD with the Tablo® System on a 4 times per week schedule. The applicant explained that the trial consisted of 4 treatment periods: (1) A 1 week, in-center run-in period; (2) an in-center period of 32 treatments (approximately 8 weeks) during which ESRD facility staff managed the dialysis treatments; (3) a transition period of up to 4 weeks to train the patient and care partner in managing the dialysis; and (4) a final in-home period of 32 treatments (approximately 8 weeks).

With respect to the applicant's secondary sources of support, a poster presentation from Alvarez, et al., presented dialysis adequacy data collected from a retrospective review of 29 patients' (18 males, 11 females and 17 percent Black, 10 percent Hispanic) dialysis records. The study compared Kt/V results of patients aged 34–84 receiving dialysis using the Tablo® System to patients receiving dialysis from a conventional HD machine. The majority of patients used a fistula or graft (59 percent fistula, 28 percent graft, 10 percent catheter). One hundred ninety two dialysis treatments were conducted on a thrice-weekly schedule using the Tablo® System with a dialysate flow rate of 300 mL per minute. A single pool Kt/V of greater than 1.2 was achieved in 94 percent of treatments in patients less than 90 kg with an average duration of treatment at 224 +/−29 minutes and in 79 percent of treatments in patients greater than 90 kg with an average duration of treatment at 249 +/−27 minutes. The average achieved Kt/V was 1.4 +/−0.2 among treatments provided with the Tablo® System. Eighty-eight treatments were conducted using a conventional HD machine with a dialysate flow rate of 500 mL per minute. A single pool Kt/V of greater than 1.2 was achieved in 93 percent of treatments in patients less than 90 kg with an average duration of treatment at 227 +/−21 minutes and in 83 percent of treatments in patients greater than 90 kg with an average duration of treatment at 249 +/−14 minutes. The average achieved Kt/V was 1.6 +/−0.4 among the conventional HD treatments.[29]

Next, an article from Chertow, et al., described additional data from the Tablo® System IDE study (discussed previously), including health-related quality of life, to further assess the safety of home HD with the Tablo® System. Demographic information identified the mean age as 49.8 + 13 years, 62 percent male, 62 percent White, 38 percent Black or African American, 23 percent Hispanic or Latino, 68 percent Not Hispanic or Latino, and 8 percent not reported, among patients established on home HD. Among the patients new to home HD, the mean age was identified as 54.2 + 10.4 years, 65 percent male, 53 percent White, 47 percent Black or African American, 29 percent Hispanic or Latino, 71 percent Not Hispanic or Latino, and 0 percent not reported. Twenty-eight of 30 patients (93 percent) completed all trial periods. Adherence to the prescribed 4 treatments per week schedule was 96 percent in-center and 99 percent in-home. The median time to recovery was 1.5 hours during the in-center and 2 hours during the at-home phase of the trial. Median index values on the 5-level EuroQol-5 Dimension (EQ–5D–5L) (a self-assessed, health related, quality of life questionnaire) were similar during the in-center as compared to in-home dialysis at 0.832 and 0.826, respectively. Patients new to home HD had lower median values (0.751) for both in-center and in-home periods. Patients who had used home dialysis prior to the trial had higher median values during both in-center (0.903) and in-home (0.906) periods. Patients reported feeling alert or well-rested with little difficulty falling or staying asleep or feeling tired and worn out when using the Tablo® System in either environment. The authors concluded that when using the Tablo® System in-home, patients reported similar time to recovery, general health status, and sleep quality compared to using the Tablo® System in-center.[30]

Next, an article from Leypoldt, et al., described the use of uremic solute kinetic models to assess dialysis adequacy via theoretical single pool Kt/V levels when varying the dialysis blood flow rates and the patient urea volume of distribution. A comparison was made between dialysate flows of 300 and 500 mL/min at blood flows of both 300 and 400 mL/min. The patient urea volume of

[28] *Clinicaltrials.gov* website. *https://www.clinicaltrials.gov/ct2/show/NCT02460263*. Last Updated July 1, 2020. *https://www.clinicaltrials.gov/ProvidedDocs/63/NCT02460263/Prot_000.pdf.*

[29] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[30] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

distribution range modeled by the authors ranged from 25 to 45 L. Under ideal conditions, the authors demonstrated that with a blood flow of 300 mL per minute, a single pool Kt/V of greater than 1.2 could be achieved in patients with a urea volume of distribution of 35 L and 240 minutes of dialysis. Patients with a urea volume of distribution of 40 L would require 255 minutes of dialysis. Patients with a urea volume of distribution of 45 L would require over 270 minutes of dialysis. With a blood flow of 400 mL per minute, patients with a urea volume of distribution of 40 L could achieve the target single pool Kt/V of greater than 1.2 with 240 minutes of dialysis. Patients with a volume of distribution of 45 L could achieve the target with 270 minutes of dialysis. The authors did not model urea kinetics for patients with volumes of distribution greater than 45 L.[31]

Next, an article by Plumb, et al., described the Tablo® System IDE study (discussed previously). Demographic information reflected the mean age as 52.3 + 11.6 years, 19 men and the following racial and ethnic representation: 17 White, 13 Black or African American, 8 Hispanic or Latino, and 21 Not Hispanic or Latino. Comparisons among the 28 patients in this study and subsequent secondary analyses were either made between the 8 weeks of using the Tablo® System for in-center HD and the 8 weeks of the Tablo® System for in-home HD or between using the Tablo® System in-home HD and the treatment provided prior to study enrollment. In both settings, patients dialyzed using the Tablo® System 4 times per week. The primary efficacy endpoint was achievement of a weekly standard Kt/V greater than or equal to 2.1 in both the 8-week in-center phase of the study and the 8-week in-home phase of the study. This endpoint was achieved in 199 of 200 weeks in the in-center dialysis period and in 168 of 171 weeks in the in-home dialysis period. The primary safety endpoint of adverse event rates were similar at 1.9 percent in the in-center dialysis period and 1.8 percent in the in-home dialysis period. The secondary efficacy endpoint was whether the ultrafiltration volume and rate achieved the prescribed levels. In both in-center and in-home dialysis, 94 percent of treatments achieved successful delivery of ultrafiltration, defined as a rate within ten percent of the prescribed value. Of 960 in-center dialysis services and 896 in-home dialysis services, 922 and 884 were completed respectively, yielding adherence rates of 96 percent and 99 percent.[32]

Next, a separate article by Plumb et al., reported additional data from the Tablo® System IDE study (previously discussed) regarding participants' assessment of the Tablo® System's ease-of-use, the degree of dependence on health care workers and caregivers after training with the system was complete, and the training time required for a participant to be competent in self-care. Demographic information reflected the mean age as 52.6 years, 18 men, 10 women, 16 White, 7 Hispanic or Latino, 9 Not Hispanic or Latino, and 12 Black or African American. Participants were stratified according to whether they were previously on self-care dialysis at home or conventional in-center HD. Thirteen participants had previous experience performing self-care HD. The remaining 15 participants had previous experience with in-center HD only. All participants rated the Tablo® System's setup, treatment, and takedown on a scale from 1 (very difficult) to 5 (very simple) and indicated whether they had required assistance with treatment over the prior 7 days. Set up times were similar regardless of whether the participants were previously on self-care HD or conventional in-center HD. For the participants previously on in-center HD, the average set up time for the concentrates was 0.93 minutes and for the cartridge, 9.35 minutes. For participants previously on self-care home HD, the average set up time for the concentrates was 1.22 minutes and for the cartridge, 10.28 minutes. The average rating of the Tablo® System's ease of use for setup was 4.5, treatment 4.6, and take down 4.6 among the participants previously on self-care home HD. In comparison, based on recollection (not based on rating during time of use) these participants' average rating of their previous device's ease of use for setup was 3.5, treatment 3.3, and take down 3.8. The average rating of the Tablo® System's ease of use for setup and treatment was 4.6 and 4.7 for take down among participants without prior self-care experience.

Among patients surveyed, caregiver assistance was required in 62 percent of patient-weeks during home self-care. Participants previously on self-care home HD required some caregiver assistance in 42 percent of the in-home dialysis treatment weeks. Participants previously on conventional in-center dialysis required some caregiver assistance in 35 percent of the in-home dialysis treatment weeks. The requirement for some form of assistance among participants with or without previous self-care experience was not meaningfully different. Finally, the authors noted that a protocol amendment allowed for the recording of the number of training sessions necessary to deem a patient competent to do self-care dialysis. This recording was limited to the last 15 participants enrolled into the study. Five of these participants had previous self-care dialysis at home experience. The average number of training sessions required to be deemed competent was 3.6 for participants with previous self-care dialysis at home experience and 3.9 sessions for participants with only conventional in-center HD experience.[33]

Next, a poster presentation from Chahal, et al., reported patient device preference of prior in-home HD patients based on data from the Tablo® System IDE study (previously discussed). The authors noted that 13 of the 30 participants in the Tablo® System IDE trial were performing in-home HD at the time of enrollment and that prior to the study, dialysis prescriptions averaged 4.5 treatments per week with an average time of 3.1 hours per session. Trial prescriptions were for 4 days per week and an average of 3.4 hours per session. Adherence to the study regimen was 97 percent and 92 percent of surveys were completed. The authors concluded that participants with prior home HD experience preferred the Tablo® System compared to their prior device and 85.6 percent found that the Tablo® System was easier to use.[34]

As stated previously in the CY 2022 ESRD PPS proposed rule (86 FR 36337), the applicant submitted several sources pertaining to the incumbent, NxStage®. First, an article from Kraus et al., described a feasibility study to demonstrate the safety of center-based versus home-based daily HD with the NxStage® portable HD device. This retrospective analysis examined the extent to which clinical effects

[31] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[32] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[33] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[34] Chahal, Y., Plumb, T., Aragon M. (2020). Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial. Poster Presentation at National Kidney Foundation Spring Clinical Conference, March 2020.

previously associated with short-daily dialysis were also seen using the NxStage® device. The authors conducted a prospective, two-treatment, two-period, open-label, crossover study of in-center HD vs. home HD in 32 patients treated at six U.S. centers. Demographic information reflected the mean age as 51 years, 63 percent male, 38 percent female, 24 White, 6 Black or African American, 1 American Indian or Alaskan native, and 1 Asian. The 8-week In-Center Phase (6 days/week) was followed by a 2-week transition period and then followed by the 8-week Home Phase (6 days/week). Data was collected retrospectively on HD treatment parameters immediately preceding the study in a subset of patients. Twenty-six out of 32 patients (81 percent) successfully completed the study. Treatment compliance (defined as completing 43 to 48 treatments in a given phase) was comparable between the 2 treatment environments (88 percent In-Center vs. 89 percent Home). Successful delivery of at least 90 percent of prescribed fluid volume (primary endpoint) was achieved in 98.5 percent of treatments in-center and 97.3 percent at home. Total effluent volume as a percentage of prescribed volume was between 94 percent and 100 percent for all study weeks. The composite rate of intradialytic and interdialytic adverse events per 100 treatments was significantly higher for the In-Center Phase (5.30) compared with the Home Phase (2.10; p=0.007). Compared with the period immediately preceding the study, there were reductions in blood pressure, antihypertensive medications, and interdialytic weight gain. The study concluded that daily home HD with a small, easy-to-use HD device is a viable dialysis option for ESRD patients capable of self/partner administered dialysis.[35]

Second, an article from Finkelstein et al., reported on interim results of the Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements (FREEDOM) study, a multi-center, prospective, cohort study of at-home short daily HD with a planned 12-month follow-up (*ClinicalTrials.gov* identifier, NCT00288613). Eligible patients were adults with ESRD requiring dialysis who were being initiated on short daily HD (prescribed 6 times per week) at home using the NxStage® cycler and who had Medicare as their primary insurance payer. The authors examined the long-term effect of short daily HD on health-related quality of life, as measured by the Short Form–36 (SF–36) health survey. The survey was administered at baseline, 4 and 12 months after initiation of short daily HD to 291 (total cohort) participants. Demographic information reflected the mean age as 53 years, 66 percent male and 70 percent White. Of the 291 participants, 154 completed the 12-month follow-up (as-treated cohort).

In the total cohort analysis, both the physical- and mental-component summary scores improved over the 12-month period, as did all 8 individual domains of the SF–36. The as-treated cohort analysis showed similar improvements with the exception of the role-emotional domain. Significantly, in the as-treated cohort, the percentage of patients achieving a physical component summary score at least equivalent to the general population more than doubled. The authors concluded by noting that at-home short daily HD is associated with long-term improvements in various physical and mental health-related quality of life measures.[36]

Third, in Weinhandl, et al., authors described a cohort study in which 4,201 new home HD patients in 2007 were matched with 4,201 new PD patients in 2010 from the United States Renal Data System (USRDS) database to assess relative mortality, hospitalization, and technique failure. Demographic information reflected the mean age as 53.8 + 14.9 years, 67 percent male, 33 percent female, 24.4 percent Black, and 75.6 percent Nonblack. Daily home HD patients initiated use of NxStage® from 2007 through 2010. Authors reported home HD was associated with 20 percent lower risk for all-cause mortality, 8 percent lower risk for all-cause hospitalization, and 37 percent lower risk for technique failure, all relative to PD. Regarding hospitalization, risk comparisons favored home HD for cardiovascular disease and dialysis access infection and PD for bloodstream infection. Authors noted that matching was unlikely to reduce confounding attributable to unmeasured factors, including residual kidney function; lack of data regarding dialysis frequency, duration, and dose in daily home HD patients and frequency and solution in PD patients; and diagnosis codes used to classify admissions. The authors concluded that these data suggest that relative to PD, daily home HD is associated with decreased mortality, hospitalization, and technique failure but that risks for mortality and hospitalization were similar with these modalities in new dialysis patients.[37]

Fourth, in Suri et al., 1116, daily home HD patients were matched by propensity scores to 2,784, contemporaneous USRDS patients receiving home PD. The authors compared hospitalization rates from cardiovascular, infectious, access-related or bleeding causes, and modality failure risk. Similar analyses were performed for 1,187, daily home HD patients matched to 3,173, USRDS patients receiving in-center conventional HD. Demographic information identified the mean age as 50.5 years, 67.3 percent male, 70.9 percent White, 26.6 percent Black, and 2.5 percent Other, among the daily home HD patients. Among the home PD patients, the mean age was identified as 50.9 years, 66.9 percent male, 73.1 percent White, 25.1 percent Black and 1.2 percent Other. The composite hospitalization rate was significantly lower with daily home HD than with PD (0.93 vs. 1.35/patient-year). Daily home HD patients spent significantly fewer days in the hospital than PD patients (5.2 vs. 9.2 days/patient-year), and significantly more daily home HD patients remained admission-free (52 percent daily home dialysis vs. 32 percent PD). In contrast, there was no significant difference in hospitalizations between daily home HD and conventional HD (0.93 vs. 1.10/patient-year). Cardiovascular hospitalizations were lower with daily home HD than with conventional HD (0.68) while infectious and access hospitalizations were higher (1.15) and 1.25 respectively). Significantly more PD than daily home HD patients switched back to in-center HD (44 percent vs. 15 percent). In this prevalent cohort, daily home HD was associated with fewer admissions and hospital days than PD, and a substantially lower risk of modality failure.[38]

(b) Applicant Substantial Clinical Improvement Claims

Regarding the applicant's first claim that the Tablo® System decreases treatment frequency with adequate

[35] Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[36] Finkelstein, F.O., et al. (2012). At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney International, 82(5), 561–569.

[37] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: a matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[38] Suri, R.S., Li, L., & Nesrallah, G.E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney International, 88(2), 360–368.

dialysis clearance, the applicant stated that the Tablo® System is the only mobile HD device approved for use in the home that can achieve adequate dialysis in as little as 3 treatments per week, while also providing flexibility for more frequent dialysis and thus greater personalization of care. The applicant stated that adequate dialysis for a standard, thrice-weekly treatment schedule is a single treatment clearance of urea, expressed as a single-pool Kt/V (spKt/V) of greater than 1.2 where ''K'' = dialyzer clearance, ''t'' = time, and ''V'' = Volume of distribution of urea. The applicant also stated that dialyzer clearance, or ''K'', is dependent on the mass transfer coefficient (KoA) characteristics of the prescribed dialyzer and prescribed blood and dialysate flow rates. The applicant further noted that limitations in ''K'' or ''t'' affect the ability of a patient to achieve adequate clearance during a dialysis treatment. Per the applicant, across a broad range of weights, patients using the Tablo® System can achieve the target of dialysis adequacy, a single pool Kt/V of 1.2, with 3 treatments per week in less than 4 hours.[39] The applicant also stated that when used 4 times per week, patients using the Tablo® System had a higher mean weekly standard Kt/V with equivalent or better dialysis-related hospitalization rates,[40] as compared to NxStage® IDE patients prescribed therapy at 6 days per week.[41]

The applicant stated that the Tablo® System's on-demand dialysate production has no limitation to the volume of dialysate that can be produced and used during a single treatment. The applicant further stated that this facilitates the delivery of adequate dialysis clearance (Kt/V) in a standard duration and target frequency of 3 times per week, as well as alternate frequencies and durations as preferred by a patient or recommended by a health care provider.

The applicant asserted that NxStage,® when attached to its PureFlow™ device, requires users to batch a set amount of dialysate (maximum of 60 liters) in advance of a treatment or use sterile dialysate bags (maximum of 30 liters). The applicant also stated that at its maximum dialysate flow rate (Qd) of 300ml/min, NxStage® greatly limits time by restricting treatment to a maximum of 200 minutes before exhausting its dialysate capacity (200 min = 60L/300ml/min). The applicant stated that Dialysis Outcomes and Practice Patterns Study (DOPPS) data demonstrate that the current U.S. practice for thrice-weekly dialysis occurs at an average treatment time of greater than 220 minutes, and has increased in the last 25 years.[42] Per the applicant, with the limited ''t'', a single-pooled Kt/V of >1.2 cannot be expected to be achieved for the majority of U.S. patients with ESRD on a thrice-weekly schedule, requiring increased treatment frequency[43] at home for these patients to meet the desired clearance level.

In citing Leypoldt, et al., the applicant stated that data from the Hemodialysis (HEMO) trial combined with modeling results from Leypoldt, et al.,[44] allowed for an estimation of the patients with ESRD, based on weight, that cannot be expected to achieve target clearance with standard thrice-weekly dialysis at this treatment duration. The applicant explained that because urea is evenly distributed throughout a body's water, the volume of distribution of urea is equal to a patient's total volume of water. The applicant also stated that total body water and volume of distribution of urea can be expressed as a volume or as a percentage of total weight and can vary based on numerous factors including disease state. The applicant stated that it is possible to estimate the percent of water for the ESRD population from the HEMO trial as summarized in Leypoldt et al.[45] The applicant stated that in the trial, the mean patient weight was 69.8kg and the mean patient volume of body water (V) was 30.9L. The applicant further explained that from this, total body water (and volume of distribution of urea) were calculated as 44.3 percent of the mean weight of patients with ESRD ($44.3 = 30.9L/69.8kg \times 100$). Per the applicant, applying this 44.3 percent of total body weight to the volumes of distribution in Leypoldt et al.[46] allowed for the conversion of the kinetic model described into anticipated patient weights. The applicant further stated that in calculating with standard blood flow and a higher dialyzer mass transfer area coefficient for urea (KoA) dialyzer, a 200 minute treatment at a dialysate flow rate (Qd) of 300ml/min would not achieve what the applicant refers to as the CMS target spKt/V target 1.2 for patients with a volume of distribution of urea (V) of 35L or greater. The applicant stated that these assumptions were drawn from NxStage® technical specifications.[47] [48] The applicant stated that at 44.3 percent of total weight, this volume of distribution of urea correlated to patients with ESRD with a mean weight above 79 kg (79 = 35L/.443) or approximately 174 pounds. Per the applicant, patients at or above this weight cannot be expected to achieve a spKt/V urea of 1.2 on a thrice-weekly schedule using the NxStage® system at its maximal dialysate flow rate.

The applicant stated that for the majority of the U.S. prevalent ESRD population between the ages of 22–74, whose mean weight is between 84.3–89.1 kg by age group,[49] thrice-weekly therapy at home on NxStage® would not achieve the Medicare coverage standard. Specifically, per the applicant, Medicare's national coverage policy is to reimburse for dialysis care 3 times per week, regardless of the modality that is used, and health care providers are expected to ensure that patients receive adequate clearance with the 3 times per week cadence. The applicant also stated that MACs have discretion in reimbursing additional treatments with medical justification.[50] Per the applicant, an analysis of Medicare

[39] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[40] Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019). Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International.

[41] NxStage Clearance Calculator. Available at: *https://dosingcalculator.nxstage.com/DosingCalculator/*. Accessed on Jan 21, 2021.

[42] Tentori F, Zhang J, Li Y, Karaboyas A, Kerr P, Saran R, Bommer J, Port F, Akiba T, Pisoni R, Robinson B. Longer dialysis session length is associated with better intermediate outcomes and survival among patients on in-center three times per week hemodialysis: Results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2012 Nov;27(11):4180–8. doi: 10.1093/ndt/gfs021. Epub 2012 Mar 19. PMID: 22431708; PMCID: PMC3529546.

[43] Health Management Associates (HMA) analysis of 2018 100% Medicare Outpatient file.

[44] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[45] Ibid.

[46] Ibid.

[47] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[48] Daugirdas JT, Greene T, Depner TA, Chumela C, Rocco, MJ, Chertow, GM for the Hemodialysis (HEMO) Study Group. Anthropometrically Estimated Total Body Water Volumes are Larger than Modeled Urea Volume in Chronic Hemodialysis Patients: Effects of Age, Race and Gender. 2003. Kidney Int. 64:1108–1119.

[49] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2*. Accessed on Jan 21, 2021.

[50] Wilk, A.S., Hirth, R.A., Zhang, W., Wheeler, J.R., Turenne, M.N., Nahra, T. A., . . . & Messana, J.M. (2018). Persistent variation in Medicare payment authorization for home hemodialysis treatments. Health services research, 53(2), 649–670.

claims data from 2018 found that despite the limitations of the reimbursement policy, Medicare paid for 5 or more treatments per week in 50 percent of home HD patients nationwide, amounting to an estimated annual cost to Medicare of $122 to $126 million.[51] However, as we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36339), based on CMS review of dialysis facility claims data, among all beneficiaries who had home dialysis treatments in 2018, 39.1 percent had 5 or more dialysis sessions at least once during any week. The overall percentage of beneficiary-weeks that had 5 or more home HD sessions in 2018 was 20.9 percent. Medicare payment for these additional sessions totaled $17 million. We noted that, as indicated in Local Coverage Determination ID L35014, ''Frequency of Dialysis'' (revised effective September 26, 2019),[52] CMS established payment for HD based on conventional treatment which is defined as 3 times per week. Sessions in excess of 3 times per week must be both reasonable and necessary in order to receive payment. Covered indications include metabolic conditions (acidosis, hyperkalemia, hyperphosphatemia), fluid positive status not controlled with routine dialysis, pregnancy, heart failure, pericarditis, and incomplete dialysis secondary to hypotension or access issues. The applicant asserted that the use of the Tablo® System would decrease the number of necessary dialysis treatments, without affecting patient outcomes such as clearance or hospitalizations.

The applicant stated that there was clinical evidence and expert consensus that as treatment frequency increases, native residual kidney function drops, patient and care partner burden increases, and vascular access complications increase.[53] [54] Per the applicant, home use of the Tablo® System could reduce the need for a fifth or sixth weekly treatment without increasing patients' symptom burden.[55] The applicant stated that by achieving adequacy targets with fewer treatments, Tablo® System patients could be expected to have fewer vascular access interventions and health care providers will have increased flexibility in personalizing the frequency and duration of patient treatments.[56] [57] The applicant stated that reducing treatment frequency while maintaining adequate patient clearance levels may also reduce complications that lead to hospitalizations. The applicant stated that during the Tablo® System IDE study, patients using the Tablo® System 4 times per week, for an average duration of less than 4 hours per treatment, had an all-cause hospital admission rate of 426 per 1,000 patient-years whereas in the general dialysis population, the all-cause admission rate was 1,688 per 1,000 patient-years, and for patients who utilized PD, the hospitalization rate was 1,460 per 1,000 patient years.[58]

The applicant stated that while NxStage® has not specifically reported the hospitalization rates per patient-year from its IDE study, published data from Weinhandl et al.,[59] and Suri et al.,[60] reported hospital admission rates amongst patients on daily home HD ranging from 930 to 1,663 per 1,000 patient-years, using a national sample of dialysis patients matched for comparison to similar peritoneal and in-center dialysis patients. We clarified in the CY 2022 ESRD PPS proposed rule (86 FR 36339–36340) that this would represent 930 to 1,663 cases observed among 1,000 persons during 1 year. The applicant also noted that all data on home patients in Weinhandl et al. came from a matched cohort of NxStage® patients. Per the applicant, in Suri et al., data were collected prior to 2015 and that during this timeframe, it could be reasonably assumed that home HD patients were using NxStage® for treatment. The applicant stated that the results from these studies suggested that patients receiving treatment at home with NxStage® 5 to 6 times per week do not have a lower all-cause hospitalization rate, relative to matched in-center HD patients. The applicant concluded by stating that because of the clinical and demographic diversity of the Tablo® System's patient population, the applicant's results showed incremental improvement over the hospitalization rate of the current home HD population.

Regarding the applicant's second claim that the Tablo® System increased adherence to dialysis treatment and retention to home therapy, the applicant stated that patients using the Tablo® System have improved adherence to prescribed treatments and a higher rate of retention to home therapy. The applicant further stated that this increased adherence and retention is likely to improve patient outcomes by reducing the rate of dialysis-related hospitalizations and other adverse events associated with missing treatment in this patient population.[61]

The applicant stated that adherence to prescribed dialysis treatments is crucial for dialysis patients because missed treatments increased the risk of dialysis dropout, hospitalization, and death.[62] Per the applicant, the Tablo® System IDE study demonstrated a 99 percent treatment adherence rate to all

[51] Health Management Associates (HMA) analysis of 2018 100 percent Medicare Outpatient file.

[52] Medicare Coverage Database. Retrieved May 24, 2021 from: *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35014&ver=39&NCDId=79&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=transplant&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAADgAAAAA&.*

[53] National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. Am J Kidney Dis. 2015; 66(5):884–930.

[54] Shafi T, Wilson RF, Greer R, Zhang A, Sozio S, Tan M, Bass EB. End-stage Renal Disease in the Medicare Population: Frequency and Duration of Hemodialysis and Quality of Life Assessment. Technology Assessment Program Project ID No. JHE51000. (Prepared by the Johns Hopkins University Evidence-based Practice Center under contract number HHSA 290–2015–00006I) Rockville, MD: Agency for Healthcare Research and Quality. July 2020. Available at: *http://www.ahrq.gov/research/findings/ta/index.html.*

[55] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[56] FHN Trial Group. (2010). In-center hemodialysis six times per week versus three times per week. New England Journal of Medicine, 363(24), 2287–2300.

[57] Kuo, T.H., Tseng, C.T., Lin, W.H., Chao, J.Y., Wang, W.M., Li, C.Y., & Wang, M.C. (2015). Association Between Vascular Access Dysfunction and Subsequent Major Adverse Cardiovascular Events in Patients on Hemodialysis: A Population-Based Nested Case–Control Study. Medicine, 94(26).

[58] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2.* Reference Table G2.

[59] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: a matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[60] Suri, R.S., Li, L., & Nesrallah, G.E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney international, 88(2), 360–368.

[61] Chan, K.E., Thadhani, R.I., & Maddux, F.W. (2014). Adherence barriers to chronic dialysis in the United States. Journal of the American Society of Nephrology, 25(11), 2642–2648. Supporting evidence of association between decreased dialysis adherence and poor patient health and utilization outcomes.

[62] Weinhandl, Eric D., Collins Allan, Incidence of Therapy Cessation among Home Hemodialysis Patients in the United States, Abstract presented, American Society of Nephrology Kidney Week 2016.

prescribed home treatments[63] among both prior in-center participants and prior self-care home HD participants who used NxStage®. The applicant also stated that the Tablo® System's adherence rates were similar among both the prior in-center and prior self-care participants. The applicant stated that these results represent a significant improvement over the treatment adherence rate reported in the NxStage® IDE, where the treatment compliance rate was defined less stringently as missing 5 or fewer treatments of the 48 possible treatments and was only 89 percent among patients at home and during the study period.[64] Per the applicant, using a comparable metric of missing 5 or fewer of all possible treatments at home, Tablo® System IDE patients at home had a 100 percent treatment compliance rate.

The applicant stated that technique failure in home HD, defined as reduced retention at home and a return to in-center care, has been high with NxStage®. Per the applicant, real world data show that technique failure occurs in 36 percent of home HD patients using NxStage® within 1 year of initiating treatment.[65] The applicant stated that this was challenging for the patient and taxing on the healthcare system that had invested in providing patients with home dialysis training and in paying for more frequent therapy.

The applicant stated that by directly comparing the Tablo® System's retention to that of NxStage®, the applicant assessed rates in the analogous IDE populations while excluding those who exited either study for reasons unrelated to the device such as receipt of a transplant or death. The applicant stated that the Tablo® System demonstrated a 97 percent (28 of 29) patient retention rate for the entire IDE study and a 100 percent retention rate in the in-home phase of the trial among both prior NxStage® users and prior in-center patients.[66] The applicant stated that in comparison, 81 percent of participants completed the NxStage® IDE study.[67]

The applicant stated that the Tablo® System's ease of use contributed to the improved adherence and retention rates and that the Tablo® System is designed to enable patients to become proficient and independent in using the Tablo® System after an average of 3.9 days.[68] Per the applicant, published NxStage® IDE data[69] reported an average of 14.5 days ''to complete device training on NxStage®.'' The applicant stated that, in comparison, device-related training time is reduced by at least 50 percent on the Tablo® System. Per the applicant, the reduced training time and ease of use would likely improve retention and potentially reduce the number of reimbursable training sessions. The applicant stated that because of the significant role that caregivers play in supporting home dialysis treatments,[70] care partner burnout and a patient's perception of being a burden is associated with discontinuation of home therapy.[71] [72]

Per the applicant, the 28 patients who entered the home phase of the Tablo® System IDE study were asked weekly if they needed help with their dialysis treatments during the prior 7 days. The applicant stated that a 96 percent response rate (216 of 224 possible) was achieved at the end of the study and that for both prior-in-center and NxStage® study participants, in 79 percent of the treatment weeks, patients reported needing no assistance from their care partner in performing dialysis set-up, treatment, or breakdown. The applicant explained that among the 13 prior in-home patients, all of whom were formerly NxStage® users, participants reported needing help from a trained individual with dialysis treatment in 69 percent of treatment weeks, with 46 percent of instances involving a need for device-related help. We clarified in the CY 2022 ESRD PPS proposed rule (86 FR 36340—36341) that per Plumb, et al.,[73] this was the baseline percentage and reflected 9 of the 13 patients with previous self-care experience. The applicant stated that patients reported needing help with treatment in only 42 percent of treatment weeks while using the Tablo® System, which was a 39 percent reduction from baseline NxStage® use; and only 18 percent of these instances related to use of the Tablo® System, which was a 61 percent reduction in rate from baseline NxStage® use.[74]

The applicant stated that it collected weekly data from patients by asking them to rate the extent to which they believed that they were a burden on a scale of 1 to 5, with 1 representing never and 5 representing always. The applicant stated that this measure was adapted from an instrument used in assessing terminally ill patients.[75] The applicant stated that the subpopulation of study participants who had previously used NxStage® reported an average score of 3.1 for self-perceived burden on their care partner when using their prior device, which subsequently reduced to 2.4 when using the Tablo® System (a 23 percent reduction in score from baseline NxStage® use).[76] Per the applicant, these data underscored that a significant increase in patients' confidence, ability to achieve treatment independence at home, and subsequent reduction in the sense of self burden can positively contributed to success in the home setting. The applicant further noted that the ease of use, reduced training time, and substantial reduction in care partner assistance required for

[63] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[64] Kraus, M., et al. A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007). The authors performed a feasibility study to demonstrate the safety of center-based vs. home-based daily hemodialysis with the NxStage System One portable hemodialysis device.

[65] Weinhandl, Eric D., Collins Allan, Incidence of Therapy Cessation among Home Hemodialysis Patients in the United States, Abstract presented, American Society of Nephrology Kidney Week 2016.

[66] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[67] Kraus M, Burkart J, Hegeman R, Solomon R, Coplon N, Moran J. A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodial Int. 2007 Oct; 11(4):468–77. doi: 10.1111/j.1542–4758.2007.00229.x. PMID: 17922746.

[68] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[69] Kraus, M., et al, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[70] Seshasai, R.K., et al. (2019) The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150 (2019).

[71] Suri, R.S., Larive, B., Hall, Y., Kimmel, P.L., Kliger, A.S., Levin, N., . . . & Frequent Hemodialysis Network (FHN) Trial Group. (2014). Effects of frequent hemodialysis on perceived caregiver burden in the Frequent Hemodialysis Network trials. Clinical Journal of the American Society of Nephrology, 9(5), 936–942.

[72] Jacquet, S., & Trinh, E. (2019). The potential burden of home dialysis on patients and caregivers: a narrative review. Canadian journal of kidney health and disease, 6, 2054358119893335.

[73] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[74] Ibid.

[75] Chochinov, H.M., Kristjanson, L.J., Hack, T.F., Hassard, T., McClement, S., & Harlos, M. (2007). Burden to others and the terminally ill. Journal of pain and symptom management, 34(5), 463–471.

[76] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

the Tablo® System correlated to the improved retention and adherence rates in the Tablo® System IDE study. The applicant stated that on a population level, this likely translated to reduced barriers to continuing home HD once initiated, and ultimately, a reduced risk of adverse outcomes due to missed treatments. The applicant also stated that the Tablo® System's electronic data capture and automatic wireless transmission eliminates the need for manual record keeping, which represented an improvement with respect to burden and monitoring as compared to NxStage®.

Regarding the applicant's third claim that the Tablo® System improved patient quality of life, the applicant stated that patients on the Tablo® System experienced reduced disease burden, dialysis related symptoms, and an improved quality of life at home as compared to in-center and existing home care options. Per the applicant, patients with ESRD experience significant dialysis-related symptoms including difficulty sleeping, dizziness, and pain associated with recovery time that affect mental and physical health and lead to decreased overall quality of life.[77] Per the applicant, the Tablo® System IDE study assessed several validated Patient-Reported Outcome Measures (PROMs) to better understand overall health-related quality of life (HR-QoL). The applicant explained that the overall measure was the EQ–5D–5L, a validated, preference-based PROM in which patients self-assess mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[78] The applicant stated that from these domains, an index value is calculated to report a summary score that ranges from 0 (death) to 1 (full health).

Per the applicant, while the NxStage® IDE study did not report results for a quality-of-life instrument, HR-QoL was assessed in NxStage® patients in a prospective multicenter observational study referred to as the FREEDOM trial, which examined the effects of at-home dialysis 6 times per week with the NxStage® System on costs and HR-QoL using the SF–36 instrument. The applicant further stated that the reported results at 4-month follow-up among these patients[79] translates to a mean EQ–5D score of 0.70. The applicant included an appendix describing the Methodology to Derive EQ–5D Scores from the FREEDOM Study Results in its application and derived a predicted mean EQ–5D score of 0.695–0.70 at follow up for the FREEDOM study. The applicant further noted that because this estimate is based on the average aggregate change for an adjusted measure that was then translated to the EQ–5D scale, and the applicant did not have access to standard error estimates for the Mental Component Score (MCS) and Physical Component Score (PCS), its interpretation of this estimate and its variance is limited. Per the applicant, nonetheless, it provided a sense of the comparable HR-QoL of this sample of NxStage® patients at follow-up. The applicant further noted that mean EQ–5D index values for traditional HD and PD patients reported from a meta-analysis of existing studies in the literature are 0.56 (95 percent CI: 0.49–0.62) and 0.58 (95 percent CI: 0.5–0.67), respectively.[80]

Per the applicant, patients in the Tablo® System IDE study reported mean EQ–5D index values of 0.821 (SD: ±0.163)[81] in the home phase of the study with final measures taken at approximately 5 months from trial start. The applicant stated that this is a significant improvement when using traditional HD patients as a comparator, and higher overall HR-QoL as compared to NxStage® patients. The applicant emphasized that participants in the Tablo® System IDE trial underwent a reduced treatment frequency as compared to participants in the FREEDOM study who were prescribed 6 treatments per week on NxStage®. The applicant stated that among patients in the Tablo® System IDE study who had previously been using NxStage®, the mean EQ–5D score during the in-home phase of the study was 0.906 (SD: ±0.119) and asserted that this is significantly greater than index population values for HD and PD.

The applicant stated that sleep problems are present in 60 percent of patients with chronic kidney disease (CKD) and ESRD[82] and that patients ranked fatigue and lack of energy as the most important contributor to their decreased quality of life.[83] Per the applicant, the frequency of sleep-related symptoms among the Tablo® System's patients was assessed by a survey that was administered weekly during the Tablo® System IDE study. The applicant stated that, in the absence of a well-validated sleep survey specific to the ESRD population, study investigators selected survey questions from previously validated sleep questionnaires in the non-ESRD population, based on their relevance to the study population.[84] [85] The applicant explained that questions were designed to focus on quality of sleep and restfulness and noted that these measures are validated for use among chronically ill populations and measure the frequency of 4 key sleep-related symptoms. The applicant stated that, while at home, patients on the Tablo® System reported improved quality of sleep, with a measurable reduction in rate of patient-reported sleep symptoms ranging from a 10–60 percent reduction, depending on symptom.[86] The applicant stated that this reduction was observed among study participants who were previously receiving dialysis in-center (average magnitude of reduction in rate across symptoms: 42 percent) and among study participants who were previously receiving in-home dialysis on NxStage® (average magnitude of reduction in rate across symptoms: 27 percent). Per the applicant, on average, sleep-related difficulties reduced from being reported in 33 percent of treatment weeks while on NxStage® to 23 percent of treatment weeks while on the Tablo® System.

[77] Gabbay, E., Meyer, K.B., Griffith, J.L., Richardson, M.M., & Miskulin, D.C. (2010). Temporal trends in healthrelated quality of life among hemodialysis patients in the United States. Clinical journal of the American Society of Nephrology, 5(2), 261–267.

[78] Yang, F., Wong, C.K., Luo, N., Piercy, J., Moon, R., & Jackson, J. (2019). Mapping the kidney disease quality of life 36-item short form survey (KDQOL–36) to the EQ–5D–3L and the EQ–5D–5L in patients undergoing dialysis. The European Journal of Health Economics, 20(8), 1195–1206.

[79] Finkelstein, F.O., et al. (2012). At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney international, 82(5), 561–569.

[80] Liem, Y.S., Bosch, J.L., & Hunink, M.M. (2008). Preference-based quality of life of patients on renal replacement therapy: a systematic review and meta-analysis. Value in Health, 11(4), 733–741.

[81] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

[82] Davison SN, Levin A, Moss AH, Jha V, Brown EA, Brennan F, Murtagh FE, Naicker S, Germain MJ, O'Donoghue DJ, Morton RL, Obrador GT; Kidney Disease: Improving Global Outcomes. Executive summary of the KDIGO Controversies Conference on Supportive Care in Chronic Kidney Disease: developing a roadmap to improving quality care. Kidney Int. 2015 Sep;88(3):447–59.

[83] Urquhart-Secord, Rachel et al (2016). Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Volume 68, Issue 3, 444–454.

[84] Morin, C.M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. Sleep, 34(5), 601–608.

[85] Natale, V., Fabbri, M., Tonetti, L., & Martoni, M. (2014). Psychometric goodness of the mini sleep questionnaire. Psychiatry and clinical neurosciences, 68(7), 568–573.

[86] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

The applicant stated that hypotensive symptoms such as feelings of dizziness and lightheadedness are associated with the drops in blood pressure that can occur during dialysis and are also among the top ten symptoms dialysis patients report that impact their quality of life.[87] Per the applicant, participants in the Tablo® System IDE study were asked at the time of enrollment regarding symptoms previously experienced during dialysis. The applicant also stated that at the end of each study treatment, participants were surveyed regarding the presence of any symptoms during that treatment on the Tablo® System. Per the applicant, a total of 8 (26.7 percent) subjects reported hypotensive symptoms during the Tablo® System treatments during the in-home treatment period, compared to 27 (90 percent) subjects reporting hypotensive symptoms at baseline (prior to initiating care on the Tablo® System). The applicant reported a 70 percent reduction in the rate of patient-reported hypotensive symptoms while on the Tablo® System, though, as we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36342), we were unable to validate the source of this statement.

The applicant stated that currently, ESRD patients on dialysis report meaningfully lower quality of life compared to those with other chronic illnesses.[88] The applicant further noted that decreased quality of life is associated with a meaningful decline in continuation of home therapy, dialysis frequency, and worse clinical and health care utilization outcomes.[89]

The applicant concluded by asserting that the totality of evidence submitted in support of the Tablo® System demonstrates substantial clinical improvement over the current standard of home dialysis care. The applicant also stated that patient preference for devices is currently used by FDA to guide marketing authorization decisions and provides important information on the benefit and risks that some patients are willing to trade when choosing a device.[90] Per the applicant, patients may be more likely to choose home dialysis to the extent that the device is both accessible and easy to use. The applicant also stated that 86 percent of prior NxStage® patients in the Tablo® System IDE study found the Tablo® System easier to use than their incumbent device and preferred to remain on the Tablo® System at the end of the study.[91]

In summary, the applicant claimed that the Tablo® System improves the treatment of Medicare beneficiaries relative to the incumbent by focusing on outcomes set forth in § 412.87(b)(1)(ii)(C), including a decreased number of treatments to achieve dialysis adequacy, which the applicant stated leads to greater adherence to prescribed therapy, and improved quality of life.

(c) CMS Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36342), after a review of the information provided by the applicant, we had identified the following preliminary concerns regarding the substantial clinical improvement eligibility criterion for the TPNIES. We noted that, consistent with § 413.236(c), CMS would announce its final determination regarding whether the Tablo® System meets the substantial clinical improvement criterion and other eligibility criteria for the TPNIES in this CY 2022 ESRD PPS final rule.

With respect to the applicant's claim that patients can achieve dialysis adequacy in as little as 3 treatments per week, we noted that the Tablo® System IDE study did not test whether patients receive adequate dialysis on a thrice-weekly schedule. Instead, data published from the Tablo® System IDE study addressed a weekly measure of dialysis adequacy among patients treated on a 4 times per week schedule. The applicant relied on modeling and unpublished data on patients receiving thrice-weekly dialysis in making the conclusion that dialysis adequacy can be reached on a thrice-weekly schedule. Specifically, the applicant referred to a theoretical modeling study based on historical data from the USRDS, Medicare claims, and historical outcomes from NxStage® observational studies. The applicant also stated that findings from a retrospective review of 29 patients receiving treatment with the Tablo® System on a thrice-weekly schedule affirmed the results from the modeling study. We also noted that the authors in Alvarez et al.[92] stated that conclusions about fluid removal could not be made from their study.

We stated that we were interested in whether additional studies were available that address issues related to effective fluid removal using home self-care dialysis thrice-weekly with the Tablo® System. We invited comments on whether less frequent dialysis sessions would represent substantial clinical improvement over shorter, more frequent sessions that, according to the applicant, were common among users of the incumbent technology.

The applicant's second claim was that the Tablo® System increased adherence to dialysis treatment and retention to home therapy, which may reduce dialysis-related hospitalizations and other adverse events associated with missing treatment. This claim was supported by the Tablo® System IDE study (28 participants completed the study) and the use of historical comparisons to prior studies involving the NxStage® System. The applicant noted that hospitalization rates from the Tablo® System IDE trial were lower than rates in the general dialysis population and rates reported in two observational studies of patients using the NxStage® device. While the applicant cited an all-cause hospitalization rate of 426 per 1000 patient years in the Tablo® System IDE study, we pointed out in the CY 2022 ESRD PPS proposed rule that it did not appear that the sources[93] [94] published these hospitalization rates. We further noted that the applicant relied on historical comparisons in asserting that that patients treated with the Tablo® System experience reduced

[87] Urquhart-Secord, Rachel et al (2016). Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Volume 68, Issue 3, 444–454.

[88] Liem, Y.S., Bosch, J.L., Arends, L.R., Heijenbrok-Kal, M.H., & Hunink, M.M. (2007). Quality of life assessed with the Medical Outcomes Study Short Form 36-Item Health Survey of patients on renal replacement therapy: a systematic review and meta-analysis. Value in Health, 10(5), 390–397.

[89] Lowrie, E.G., Curtin, R.B., LePain, N., & Schatell, D. (2003). Medical outcomes study short form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. American Journal of Kidney Diseases, 41(6), 1286–1292.

[90] Food and Drug Administration Center for Devices and Radiological Health (2020). ''Patient Preference-Sensitive Areas: Using Patient Preference Information in Medical Device Evaluation'' Available at: *https://www.fda.gov/about-fda/cdrh-patient-engagement/patient-preference-sensitive-areas-using-patientpreference-information-medical-device-evaluation*. Accessed Jan 21, 2021.

[91] Chahal, Y., Plumb, T., Aragon M. (2020). Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial. Poster Presentation at National Kidney Foundation Spring Clinical Conference, March 2020.

[92] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, Texas.

[93] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[94] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

disease burden and improved quality of life.

We noted in the CY 2022 ESRD PPS proposed rule (86 FR 36343) that in the Tablo® System IDE study, the before-after comparisons in patients with NxStage® regarding improved sleep compared to prior to the Tablo® System may be prone to recall bias in that participants' experiences with NxStage® were not recorded at the time they were receiving NxStage® treatments, but rather, were based on recall at the time of the Tablo® System IDE study.

We stated that we understood that greater flexibility for patients in the way that they receive their dialysis treatments may represent a benefit to Medicare beneficiaries who are candidates to receive this treatment in the home setting. We invited comments on whether this potential benefit represents substantial clinical improvement, including whether the Tablo® System represented an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries.

We received multiple comments on the substantial clinical improvement claims made in the TPNIES application for the Tablo® System, ranging from commenters with concerns about the claims, including from a manufacturer of a competitor device, to comments in support of the application, including from the applicant. The comments on the three substantial clinical improvement claims made by the applicant, and our responses to the comments, are set forth below.

Comment: A commenter, a manufacturer of a competitor device, asserted that the Tablo® System does not meet the substantial clinical improvement criterion. The commenter asserted that the applicant's claims were not supported by robust clinical evidence. The commenter made several criticisms about the Tablo® System IDE trial and the other clinical evidence provided by the applicant, emphasizing the lack of a direct head-to-head comparison with the NxStage® device as well as relying on theoretical modeling. For example, the commenter stated that the applicant did not submit adequate evidence to demonstrate its first claim, that decreased home HD treatment frequency with the Tablo® System offered a substantial clinical benefit for home HD patients, because the applicant's study examined patients that dialyzed on the Tablo® System more than three times per week and did not compare the Tablo® System machine to the NxStage® machine, which the commenter claimed is also capable of thrice-weekly dialysis. Further, the commenter stated that current models of the NxStage® System One™ offer dialysate flow rates of 300ml/minute and NxStage® patients can currently dialyze with any amount of dialysate prescribed by their doctor. The commenter asserted that the NxStage® machine is more flexible than the Tablo® System and that other incumbent systems, such as the Fresenius 2008K@home™, are capable of even more urea clearance than the Tablo® System in the same amount of time. Even though the commenter stated that patients using other home HD machines are able to achieve dialysis adequacy on a thrice-weekly dialysis schedule, the commenter also stated that it was not aware of any additional data in support of adequate fluid removal using a thrice-weekly dialysis schedule with the Tablo® System.

The commenter also expressed concerns with the applicant's claim that less frequent dialysis sessions may represent substantial clinical improvement over shorter, more frequent sessions because certain clinical and quality of life advancements, like more energy and vitality, are closely linked to more frequent treatments, which more closely mirror the natural function of a patient's kidney. This same point was also raised by other commenters, including health care providers. These other commenters also expressed a preference for more frequent dialysis stating that it results in increased energy levels, improved sleep and mental health, and that patients undergoing more frequent dialysis need fewer dietary restrictions and antihypertensive and phosphate binder medications. Additionally, the commenter stated that evidence suggests there is no disadvantage in access complications for patients that undergo more frequent dialysis, while also noting that the applicant did not present studies that compared vascular access with the Tablo® System to NxStage®.

The commenter stated that the applicant did not provide sufficient clinical evidence for its claim that the Tablo® System results in an incremental improvement in hospitalization rates because the sources that the applicant provided were not yet published.

Similarly, the commenter asserted that the applicant did not demonstrate that the Tablo® System increases adherence to the dialysis treatment and retention to home therapy because the studies cited by the applicant did not compare adherence, retention, or ease of use for the Tablo® System with the NxStage® or the Fresenius 2008K@home™ systems. The commenter stated that the Tablo® System IDE study on which the applicant relied to demonstrate treatment adherence and retention had several weaknesses including a small patient population, narrow patient inclusion criteria, and short duration. While the commenter acknowledged that the applicant did compare adherence rates from the Tablo® System IDE Study to adherence in the NxStage® IDE study, the commenter explained that this methodology was not appropriate because the studies had different definitions of treatment compliance. The commenter noted that the applicant's comparison of patient retention rates from the Tablo® System and NxStage® IDE studies was similarly not appropriate because the equipment used during the time of the NxStage® IDE study was completely different from that which is widely used today (that is, NxStage® touchscreen VersiHD™, Express Warmer, PureFlow™ SL).

Also, regarding the applicant's adherence claim, the commenter identified several factors that it argued may reduce dialysis adherence using the Tablo® System and restrict its use to a small subset of dialysis patients. First, the commenter stated that patients without consistent access to clean tap water may be at risk for disruptions in dialysis treatment with the Tablo® System. The commenter identified potential tap water disruptions such as water main breaks or the loss tap water during power outages for patients who rely on well-based water. The commenter further stated that water source disruptions do not hinder NxStage® patients from continuing their treatment because they can treat with pre-mixed dialysate bags. The commenter concluded that the Tablo® System's on-demand dialysate production is not a substantial clinical improvement over the NxStage® System One™ with PureFlow™ SL's on-site dialysate production. Second, the commenter stated, as did several other commenters, that the Tablo® System increases electric and water utility expenses by requiring a large volume of water to complete the reverse osmosis process and because the system must heat the water prior to use for dialysate and for sterilization after treatment. Third, the commenter stated that the Tablo® System has not received FDA marketing authorization for solo home hemodialysis (hemodialysis without a care partner) during waking hours, as well as nocturnal home hemodialysis, whereas the NxStage® System One™ has received these FDA marketing authorizations.

The commenter stated that the applicant did not provide sufficient evidence to advance its claim that the Tablo® System improves patient quality of life. The commenter stated that no comparison of incremental benefit in quality of life of the Tablo® System over NxStage® was provided. The commenter further stated that studies involving hundreds of patients have been specifically designed to test quality of life outcomes, among NxStage® users and have been published in peer-reviewed journals demonstrating quality of life improvements among NxStage® users. The commenter stated that there is a high bar for relying on quality of life evidence to demonstrate innovation, recognizing the breadth of evidence that exists for current technologies. Regarding the applicant's evidence on its improved patient quality of life claim, the commenter stated that it was unable to confirm the applicant's claim of a 70 percent reduction in the rate of patient-reported hypotensive symptoms while on the Tablo® System and asserted that data also supports a reduction in intradialytic hypotensive episodes among NxStage® patients, referring to an article by Murashima et al.[95]

The commenter similarly questioned the applicant's claims regarding sleep quality and related symptoms stating that the Tablo® System IDE data did not compare the Tablo® System to NxStage, relied on a small sample size, was of short duration, and was not accurate because study results may have been affected by recall bias. Regarding the recall bias concern, additional commenters also wrote in with concurring comments. These commenters explained that participants' experiences with NxStage® were not recorded at the time they were receiving NxStage® treatments, but rather, were based on recall at the time of the Tablo® System IDE study.

Regarding the applicant's claim that the Tablo® System users spend less time in training compared to existing technologies, the commenter questioned the applicant's reference to 14.5 days to complete training on NxStage, stating that this timeframe includes training about aspects of home dialysis beyond the functionality of the machine. The commenter stated that only approximately 5 session-equivalents are machine-focused during training with NxStage®. The commenter also stated that because 13 patients in the Tablo® System IDE study had previous home HD experience, the study participants would have already been trained on the most difficult aspects of home therapy, such as self-cannulation. Therefore, the commenter suggested review of a larger number of patients who are truly new to home therapy.

The commenter rejected the applicant's assertions that the Tablo® System's features are unique and stated that the applicant did not submit data demonstrating that the Tablo® System is easier to use than other devices. The commenter stated its belief that many aspects of the Tablo® System are more difficult to use than NxStage® and highlighted key features that have become available since publication of the NxStage® IDE study. The commenter also challenged the applicant's description of the Tablo® System's cartridge as being ''pre-strung'' compared to existing cartridges and stated that NxStage® offers a cartridge that requires 4 fewer blood tubing connections. The commenter also stated that NxStage® systems are the only home HD systems approved for self-treatment without a care partner, addressing partner fatigue.

The commenter and several members of the public identified the ability to travel as a quality of life issue. They stated that because the Tablo® System weighs nearly 200 pounds, it is not portable, while the NxStage® device is lighter and portable. Due to its portability, the competitor commenter added that 70 percent of NxStage® users reported traveling while using the machine.

Finally, this commenter stated that while certain patients may prefer certain features of the Tablo® System, the presence of an additional option for home dialysis machine does not in itself represent a clinical improvement.

Response: We appreciate the input provided by the commenters. We have taken this information into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1), and have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section of the final rule.

Comment: We received a comment from the applicant in support of the TPNIES approval for the Tablo® System.

With respect to the claim that patients can achieve dialysis adequacy in as little as three treatments per week and the concern we expressed in the CY 2022 ESRD PPS proposed rule that the Tablo® System IDE study did not test whether patients receive adequate dialysis on a thrice-weekly schedule, the applicant clarified that the intent was not to position three times per week home dialysis as substantial clinical improvement over short daily or more frequent dialysis. Instead, their claim is that more frequent dialysis, which they believe is a requirement for NxStage, is significantly more burdensome for patients with ESRD for whom thrice-weekly treatments may be appropriate.

The applicant stated that the Tablo® System's ability to achieve Kt/V targets of 1.2 on a thrice-weekly treatment schedule at home represents substantial clinical improvement because they believe it allows patients the benefits of home dialysis whether administered three or four times per week, which had not been an option previously because of the technical limitations of the NxStage® system. Specifically, per the applicant, on a standard treatment duration, three day per week schedule patients with weights above 79kg do not have sufficient dialysate with NxStage® (maximum of 60L) to achieve the CMS mandated target without increasing the amount of time per treatment that the patient has to dialyze. The applicant further stated that the Tablo® System can achieve levels of efficiency nearly on par with in-center hemodialysis on conventional hardware. The applicant also noted that patients treated with NxStage® would exhaust its dialysate at 3 hours 20 minutes at an equivalent dialysate flow rate of 300ml/min. In support of that claim, the applicant referred to kinetic modeling, the clearance kinetics of the NxStage® dialyzer, and the percentage of body water[96] [97] in patients weighing 174 pounds or greater. The applicant concluded that patients treated with NxStage® would require greater than thrice-weekly treatments to achieve hemodialysis adequacy with spKt/V of >1.2. The applicant stated that because the Tablo® System is able to generate dialysate on demand at 300ml/min for up to 12 hours without volume limitations, it allows patients the flexibility to adequately dialyze at the frequency that is best for them rather

[95] Murashima M, Kumar D, Doyle AM, Glickman JD. Comparison of intradialytic blood pressure variability between conventional thrice-weekly hemodialysis and short daily hemodialysis. Hemodial Int. 2010 Jul;14(3):270–7. doi: 10.1111/j.1542–4758.2010.00438.x. PMID: 20337744.

[96] Leypoldt, J. K., Prichard, S., Chertow, G. M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376. Depner T, Beck G, Daugirdas J, Kusek J, Eknoyan G. Lessons from the Hemodialysis (HEMO) Study: an improved measure of the actual hemodialysis dose. Am J Kidney Dis. 1999 Jan;33(1):142–9.

[97] Depner T, Beck G, Daugirdas J, Kusek J, Eknoyan G. Lessons from the Hemodialysis (HEMO) Study: an improved measure of the actual hemodialysis dose. Am J Kidney Dis. 1999 Jan;33(1):142–9.

than requiring them to perform more frequent treatments.

The applicant stated that their evidence on achieving Kt/V of 1.2 on a conventional three times per week dialysis schedule came from an observational study conducted on an in-center patient population using the Tablo® System prior to its FDA marketing authorization for home HD. The applicant referred to abstracts presented at the 2019 Annual Dialysis Conference as summarized in the CY 2022 ESRD PPS proposed rule. The applicant emphasized that evidence from published and unpublished sources may be sufficient in establishing substantial clinical improvement.

In response to concerns regarding the sufficiency of the clinical evidence presented, the applicant commented that because the patient population in the Tablo® System IDE study, was more diverse and reflective of the general dialysis population with respect to diabetes and other comorbidities than the population in the NxStage® IDE study, study results regarding Tablo® System can be better applied to the Medicare population.

In their application, the applicant claimed that Tablo® System patients can be expected to have fewer vascular access interventions, and health care providers will have increased flexibility in personalizing the frequency and duration of patient treatments.[98] [99] The applicant emphasized in its comment that Tablo® System users may experience reduced vascular access infection related hospitalizations, relying on data from the Tablo® System IDE study. The applicant stated that patients prescribed 5–6 days weekly dialysis sessions with NxStage® who were converted to 4 weekly dialysis sessions with the Tablo® System, experienced no hospitalizations during the home arm of the trial. The applicant commented that these data were not included in the Tablo® System IDE publication because the sample size was modest and relatively few patients required hospitalization. The applicant also stated that 14 of the 35 patients enrolled in the NxStage® IDE dropped out before completing the trial, making it difficult to calculate an unbiased estimate of the hospitalization rate. The applicant compared the Tablo® System IDE hospitalization rate to two North American observational studies by Weinhandl et al.[100] and Suri et al.[101] of patients receiving home HD (likely NxStage® or K@Home). The applicant further stated that Suri et al. reported a hospitalization rate of 930 per 1000 patient-years and Weinhandl et al. noted a rate of 1663 per 1000 patient-years. The applicant stated that results from these studies suggest that patients receiving treatment at home with NxStage® 5–6 times per week had similar, not lower, rates of hospitalization relative to matched patients receiving in-center hemodialysis. The applicant further noted that the modest sample size of the Tablo® System IDE precludes valid inference testing, but that the hospitalization rate observed (426 per 1000 patient-years) was roughly one-quarter that seen among a national cohort of patients on home HD in the US, and less than one-half that seen among a Canadian cohort, despite the high proportion of non-white patients and patients with diabetes, characteristics typically associated with higher rates of hospitalization.

With respect to the claim that the Tablo® System increases adherence to dialysis treatment and retention to home therapy, the applicant provided additional support. Specifically, the applicant stated that in its real-world home population, to date, no patients have chosen to return to in-center HD once going home with the Tablo® System. The applicant submitted new data to further establish first-year attrition comparisons. The applicant stated that it contracted with a third-party research firm [102] to conduct an analysis of patients dialyzing at home using the Tablo® System, matched to patients in the USRDS who completed home HD training between the years 2016 through 2018. Per the applicant, home HD attrition was defined as either death or conversion to in-facility HD and kidney transplantation was excluded from attrition. The applicant further stated that the cohort included 39 patients that initiated home HD with the Tablo® System since the device's FDA marketing authorization for home use in March of 2020.

The applicant further clarified that this patient population is separate and distinct from the participants in the Tablo® System IDE study. The applicant stated that there were 4 attrition events among the 39 Tablo® System users and 3,602 attrition events among the 9,827 home HD starts in the broader population of patients receiving home HD. The applicant further noted that the cumulative incidence of attrition at 1 year was 26.8 percent among Tablo® System users and 42.5 percent among all home HD starts with the unadjusted Cox regression hazard ratio of home HD attrition among Tablo® System users versus home HD starts in years 2016 through 2018 at 0.38 (95% confidence interval, 0.14–1.02; $p = 0.06$), a more than 60 percent reduction in attrition with the Tablo® System. The applicant also acknowledged that the limited sample size reduces power in demonstrating a statistically significant result, but asserted that the preliminary data suggest that use of the Tablo® System should reduce home HD attrition.

In the CY 2022 ESRD PPS proposed rule, CMS acknowledged the applicant's claim regarding the benefit of greater flexibility for patients in the way that they receive their dialysis treatments. The applicant stated in their comment that the Tablo® System represents substantial clinical improvement over NxStage® in several ways: Allowing patients, in consultation with their clinicians, to develop a treatment schedule tailored to their individual needs, reducing the time spent on dialysis-related tasks including the elimination of a 6–8 hour pre-treatment dialysate production, and reducing supply storage requirements.

With respect to the claim that the Tablo® System improves patient quality of life, the applicant stated in their comment that Tablo® System IDE showed favorable effects on patient-reported outcomes, including the EQ–5D survey instrument that has been widely applied to many chronic disease populations, as well as a number of surveys related to the process of home dialysis.

The applicant's comment included the results from an online survey conducted by a third-party research firm [103] and a network of dialysis organizations and regional offices [104] between July 29 and August 9, 2021. Per

[98] FHN Trial Group. (2010). In-center hemodialysis six times per week versus three times per week. New England Journal of Medicine, 363(24), 2287–2300.

[99] Kuo, T.H., Tseng, C.T., Lin, W.H., Chao, J.Y., Wang, W.M., Li, C.Y., & Wang, M.C. (2015). Association Between Vascular Access Dysfunction and Subsequent Major Adverse Cardiovascular Events in Patients on Hemodialysis: A Population-Based Nested Case-Control Study. Medicine, 94(26).

[100] Weinhandl, E. D., Gilbertson, D. T., & Collins, A. J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: a matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[101] Suri, R. S., Li, L., & Nesrallah, G. E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney international, 88(2), 360–368.

[102] Analysis conducted by the Chronic Disease Research Group (CDRG), a division of the Hennepin Healthcare Research Institute.

[103] Health Advances, US Home Hemodialysis Nephrologist and Patient Perspectives Presentation, August 13, 2021.

[104] National Kidney Foundation.

the applicant, 184 nephrologists and 202 patients were surveyed regarding a list of potential benefits and system features of a blinded home HD system concept reflecting the features of the Tablo® System. The applicant stated that 77 percent of nephrologists rated the Tablo® System's features as a substantial clinical improvement in home HD care and 98 percent indicated that the Tablo® System's benefits would make them more likely to recommend home HD to their patients. The applicant further stated that 72 percent of patients receiving in-center HD or PD rated the Tablo® System's features as a significant improvement in home HD care and 77 percent of those patients stated they would be more likely to try home HD. The applicant stated that of the current home HD population dialyzing on the incumbent device, 84 percent rated the Tablo® System's features as a significant improvement in home HD care.

The applicant's comment acknowledged that NxStage® would be an available option to patients who prefer to travel with a home dialysis device but stated that the majority of patients ranked the effectiveness of treatment above the ability to travel with their device.

With respect to CMS's recall bias concern that participants' experiences with NxStage® were not recorded at the time they were receiving NxStage® treatments, but rather, were based on recall at the time of the Tablo® System IDE study, the applicant clarified that 13 of the 29 Tablo® System IDE study participants who completed the trial had been dialyzing at home with NxStage® in advance of the Tablo® System IDE study and that baseline surveys were taken while patients were actively treating with NxStage®. The applicant commented that survey questions were sourced from validated sleep questionnaires and did not ask patients for a comparison to a prior time point, but focused on a rating of sleep during the prior week.

The applicant commented that to further assess the prevalence of sleep related symptoms in home HD patients, a third-party research firm conducted a survey of current non-Tablo® System HD patients. The applicant stated that of home HD respondents, 64 percent reported very poor to poor sleep quality and all respondents stating that improved sleep would represent substantial clinical improvement.[105] The applicant stated that collectively, its results confirm that achieving satisfactory sleep remains a major challenge for patients on dialysis and that using the Tablo® System has the potential to improve sleep quality, which may also enhance physical, cognitive, and sexual function, and expand functional capacity.

The applicant's comment emphasized the safety features and ease-of-use of the Tablo® System. The applicant stated that the Tablo® System offers patients a differentiated level of safety in having met higher, more updated safety standards of performance, such as fluid removal, air detection, temperature, dialysate flow rate and other parameters than the previously approved NxStage® device. The applicant also stated that the remote monitoring and remote technical support features are only available with the Tablo® System and reduce patient apprehension to perform treatments at home. The applicant's comment again asserted that, overall, the totality of the evidence demonstrates that the Tablo® System offers substantial clinical improvement in home HD treatment.

Response: We thank the applicant for their comment and have taken the additional information provided into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section (II.C.5.c) of the final rule.

Comment: We received many comments from clinicians, patients, and caregivers supporting the Tablo® System's TPNIES application. For example, many commenters stated that using the Tablo® System is convenient and allows for the flexibility to personalize treatment for a diversity of patient needs. Commenters stated that patients are allowed to create their own schedules, which enables them to continue working and enjoying life's activities. Patient commenters stated that they have become more active and engaged participants in their own care. Commenters appreciated the convenience and comfort of being able to dialyze at home instead of in-center, stating that doing so alleviates stress, reduces exposure to COVID–19 and reduces the burden of arranging for and traveling to in-center treatments.

Patient and caregiver commenters expressed appreciation for the Tablo® System's on-demand dialysate for several reasons. First, commenters stated that patients have more dialysis-free time by not needing to prepare solution or handle heavy bags of dialysate. Second, commenters stated that there are fewer supplies to store for the Tablo® System as compared to the NxStage® System for which it was necessary to store up to 20 boxes of dialysate and supplies. Third, commenters stated that dialysate delivery may be challenged in regions with extreme climates and could compromise treatment. Commenters also stated that there is less wasted dialysate with use of the Tablo® System.

Patient commenters identified several clinical improvements that they attribute to treatment with the Tablo® System including reduced cramping and fatigue after dialysis treatment, reduced need for blood pressure medication, improved mood, and less frequent use and wear on the vascular access site with fewer weekly treatments. Commenters also stated that that features and conveniences of the Tablo® System result in less burn out[106] of patients and caregivers, better adherence, retention and overall quality of life.

Many commenters including patients, caregivers and clinicians commented on the Tablo® System's features and ease-of-use. Commenters stated that the complexity of a dialysis machine and lengthy training can be intimidating and act as a deterrent in the adoption of home dialysis. Commenters stated that some patients and caregivers cannot afford extended absences from work, childcare or other responsibilities to complete dialysis training and that training with the Tablo® System ranges from 10 days to 2 weeks compared to training with NxStage® which averages 4–6 weeks. Several commenters stated that patients with prior home dialysis experience can begin home treatments using the Tablo® System after just 3–4 training days. One commenter stated that a comparison of training for the Tablo® System versus other devices in the market does not exist.

Commenters stated that patients may also fear not being able to remember what to do in an urgent situation and highlighted the Tablo® System's safety features that prevent patient harm, including step-by-step instructions with less memorization, and fewer treatment steps, and 24/7 technical support.

[105] Health Advances, US Home Hemodialysis Nephrologist and Patient Perspectives Presentation, August 13, 2021.

[106] As discussed in the CY 2021 ESRD PPS final rule (85 FR 71462), a significant challenge to increasing the use of home dialysis includes burn out (or technique failure) and return to in-center HD. According to one recent observational study, approximately 25 percent of patients who initiate home HD return to in-center HD within the first year (Seshasai RK, Mitra N, Chaknos CM, Li J, Wirtalla C, Negoianu D, Glickman JD, Dember LM. Factors Associated With Discontinuation of Home Hemodialysis. Am J Kidney Dis. 2016 Apr;67(4):629–37.)

Commenters stated that remote treatment monitoring in real time, allows clinicians to intervene as needed with treatment modifications. Commenters stated that the Tablo® System's instructions can be set in other languages. Commenters also expressed appreciation for the Tablo® System's built-in warmer that helps to prevent hypothermia during treatment, built-in blood pressure monitoring, flush feature, closed loop cartridge to minimize risk of infection, automatic record keeping, and the quicker set up and take down times. Commenters stated that the Tablo® System looks less like an intrusive medical device and the built-in wheels make it easy to move it from room to room.

One commenter stated that patients previously not deemed suitable for home HD, due to large body size, work schedules, etc. may now become candidates with the use of the Tablo® System. Another commenter stated that patients lacking social support and financial resources may not be good candidates for home dialysis.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section (II.C.5.c) of the final rule.

Comment: We received several comments from health care providers and patients regarding the Tablo® System and less frequent dialysis treatments. A physician commenter stated that the question of whether less frequent dialysis is clinically preferable to shorter, more frequent [dialysis] sessions does not appear to be definitively decided in clinical research for all patients. The commenter stated that while patients derive significant benefit from more frequent dialysis, having the ability to achieve at least adequate dialysis at three days per week is a significant advancement compared with what has been offered. Commenters stated that the treating clinician remains in the best position to prescribe the appropriate frequency of dialysis for their patients but that it is possible for researchers to accurately assess improvements in clinical outcomes related to frequency of dialysis treatments. A commenter, who is a health care provider, shared their experience with the Tablo® System in a dialysis unit, stating that their unit tested the Tablo® System and found that on the whole, the patients could reach dialysis adequacy on a traditional thrice-weekly frequency. While this commenter referred to an abstract documenting these results, it was not provided.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section (II.C.5.c) of the final rule.

Comment: We received several comments from the public, including health care providers and patients, regarding how to demonstrate substantial clinical improvement in connection with a home hemodialysis machine such as the Tablo® System. One commenter stated that clinical trials, abstract data and expert opinion is sufficient to support substantial clinical improvement and that this type of evidence is often the basis of clinical guidelines from the National Kidney Foundation (NKF) Kidney Disease Outcome Quality Initiative. The commenter stated that new companies are not equipped to conduct in-depth studies until they have significant numbers of patients on their device or therapy which creates a barrier to recruiting study participants and thus, limiting investment in the new technology. Another commenter stated that the ESRD sector does not easily lend itself to robust clinical trials, and this fact should be considered when determining whether an applicant for TPNIES has demonstrated substantial clinical improvement. Commenters referred to the CMS TPNIES application template, which indicates that published, unpublished, and clinical expertise are all acceptable forms of supporting evidence and that placing a heavy emphasize on published long-term studies for purposes of evaluating substantial clinical improvement limits the ability of new companies to enter the market and deprives patients of potentially lifesaving technologies. A non-profit dialysis association stated that CMS should consider the extent to which the technology has demonstrated improved quality of life in determining whether the technology represents substantial clinical improvement.

Many commenters stated that patients should be given a choice in deciding which home hemodialysis machine is best for them, and that providing patients with an additional choice is evidence of substantial clinical improvement. A physician commenter indicated that it is not clear why patients prefer one machine over another or feel better with one prescription over another, but a choice based on patient preference can improve patient retention to a particular therapy, one of the ways to demonstrate substantial clinical improvement. This commenter stated that evidence that a home dialysis machine improves retention should be sufficient evidence to approve the TPNIES for that home dialysis machine.

Response: We appreciate the commenters' input regarding whether the Tablo® System meets the innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1). After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2022 ESRD PPS proposed rule, as well as the many comments submitted by the public, we agree with the applicant and several members of the dialysis community that the Tablo® System represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. We find that the data submitted demonstrate greater medication adherence or compliance of home HD among users of the Tablo® System that is not as evident for users of existing home HD technologies, as specified under § 412.87(b)(1)(C)(7). We also believe that the Tablo® System may provide added flexibility around the frequency and duration of home HD that could benefit some patients, specifically, patients who may prefer fewer, slightly longer treatments but who would otherwise be limited to more frequent home HD treatments. We believe additional flexibilities around home HD treatments may represent an improvement in one or more activities of daily living and an improved quality of life for Medicare beneficiaries, as specified under § 412.87(b)(1)(C)(4) and § 412.87(b)(1)(C)(5), respectively. We also recognize that patient preference and choice is especially important for patients with ESRD, who undergo demanding, often grueling, dialysis therapy, and we believe that patients who prefer their method and frequency of dialysis are more likely to adhere to the therapy, and thus increase adherence rates overall.

We acknowledge the concerns raised by commenters regarding the substantial clinical improvement claims in the Tablo® System application. As we had previously noted in the CY 2022 ESRD PPS proposed rule, we had some of the same concerns as commenters regarding

the evidence submitted to support the claims of significant clinical improvement. However, at this time, we feel that our concerns have been sufficiently addressed. For example, with respect to the applicant's claim that the Tablo® System increases adherence to dialysis treatment and retention to home therapy, although the adherence and retention data provided in the initial application had limitations, additional information was submitted by the applicant to support this claim in its comment on the CY 2022 ESRD PPS proposed rule. This data showed lower attrition rates at 1 year between patients using the Tablo® System for home HD, separate from the group of patients in the Tablo® System IDE, matched with patients who had completed home HD patients, using data from the USRDS. With respect to the applicant's claim that the Tablo® System improves patient quality of life, we note that the applicant addressed our concerns about the potential for recall bias in their claim of improved sleep quality and related symptoms in their comment, explaining that baseline surveys were taken while patients were actively treating with NxStage®. Also, while some commenters opposed the applicant's use of unpublished data to support its claim of improved hospitalization, we note that under § 413.236(b)(5) and 412.87(b)(1)(iii), CMS may consider unpublished data in making a determination of substantial clinical improvement as we recognize in some situations, published data may not be available. Overall, we believe the applicant was able to address our concerns about its substantial clinical improvement claims from the discussion in the CY 2022 ESRD proposed rule.

We also note that, under our TPNIES policy and § 412.87(b)(1)(i), CMS is required to consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. We believe the circumstances we may consider in our review of the TPNIES applications, specifically within the context of the ESRD PPS, include the state of the ESRD landscape and the particular challenges and vulnerabilities of patients with ESRD. While we recognize that published studies and randomized controlled trials are often the gold standard in demonstrating superiority of one product over another, our review is not limited to evidence from large randomized controlled trials; we also consider a range of evidence from published or unpublished information sources, including other appropriate information sources not otherwise listed under § 412.87(b)(1)(iii). As codified under § 412.87(b)(1)(iii), evidence from published or unpublished information sources may be sufficient to establish that a new technology represents a substantial clinical improvement.

Additional information we considered in our review of the Tablo® System was the new data provided by the applicant surveying over 180 nephrologists and over 200 patients undergoing dialysis treatment HD, along with substantial supportive comments from patients, caregivers, and health care providers, about the benefits of the Tablo® System in providing an improved quality of life, an improvement in one or more activities of daily living, and a decreased rate of at least one subsequent therapeutic intervention, as specified under §§ 12.87(b)(1)(C)(6), 412.87(b)(1)(C)(5), 412.87(b)(1)(C)(2), respectively.

We also note that, at this time, patients with ESRD are facing new, additional risks when receiving dialysis treatment due to the COVID–19 pandemic. As some of the commenters noted, ESRD patients are among the most vulnerable in the Medicare population and are at an increased risk for COVID–19 associated morbidity and mortality.[107] [108] As we discussed in the CY 2021 ESRD PPS final rule, Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID–19. As we stated in that rule, we believe it is important to reduce the risk of infection among beneficiaries with ESRD, and this can be done through isolating patients from in-center exposure by encouraging home HD (85 FR 71416). We also believe that providing patients with an additional option for home HD is especially important given that the adoption of home HD has been limited, with approximately only 1% of ESRD patients utilizing this modality.[109] Therefore, we are interested in supporting the use of technologies that expand patient options for dialyzing safely at home at this time.

For all of these reasons, we conclude that the Tablo® System meets the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(6) Capital Related Assets Criterion (§ 413.236(b)(6))

Regarding the final TPNIES eligibility criterion under § 413.236(b)(6), whether the item is a ''capital-related asset'' that is a ''home dialysis machine,'' these terms are defined in § 413.236(a)(2). The applicant identified the Tablo® System as an asset that an ESRD facility has an economic interest in through ownership, is subject to depreciation, and is an HD machine that received FDA marketing authorization for home use. We received no public comments on this criterion. We agree that the Tablo® System is a capital-related asset and home dialysis machine and therefore meets this criterion.

The remaining comments and our responses regarding the Tablo® System and its eligibility for the TPNIES are set forth below.

Comment: We received a comment that 70% of the patient population in the Tablo® System IDE study were non-white, suggesting Tablo® System's ability to create greater home adoption and retention in ways that are aligned with the proposed incentive for closing gaps in health equity access to home HD.

Response: We thank the commenter for their input. While health equity is not a specific TPNIES eligibility criteria under § 413.236(b), we strongly support health equity and believe that the approval of the Tablo® System under the criterion of § 413.236(b) will encourage uptake of home HD for vulnerable patients with ESRD.

Comment: We received several comments pertaining to the relationship between the cost of the Tablo® System and its connection to beneficiary access. Several commenters stated that the initial cost of the Tablo® System is 2 to 3 times that of older technologies, and that combined with potentially fewer treatments over which to amortize the cost, it would be difficult for ESRD facilities to incorporate the Tablo® System into their businesses without a payment adjustment under the ESRD PPS. These commenters expressed support for CMS approving the TPNIES for the Tablo® System.

The applicant stated that after the initial capital investment, the per treatment costs of using the Tablo® System are considerably less than that of the NxStage® System. Another commenter stated that the Tablo® System is more affordable than other home dialysis machines and is cost

[107] Ziemba R, Campbell KN, Tang T, et al. Excess Death Estimates in Patients with End-Stage Renal Disease—United States, February–August 2020. MMWR Morb Mortal Wkly Rep 2021;70:825–829. DOI *http://dx.doi.org/10.15585/mmwr.mm7022e2.*

[108] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/home-dialysis.html.*

[109] Mailloux LU, Blagg CR. Berns JS (ed.) Home Hemodialysis. Uptodate. Nov 18, 2016.

effective. Commenters stated that a TPNIES approval for the Tablo® System would help to offset the Tablo® System's acquisition costs, particularly for small and mid-size dialysis organizations and independent providers and facilitate economies of scale, allowing ESRD facilities to lower the cost of home HD care in the future.

Commenters also asserted that a TPNIES approval would increase home dialysis utilization and retention of patients on home dialysis, and improve clinical and patient-reported outcomes, overall. For example, several commenters stated that use of the Tablo® System may help to push the national home hemodialysis prevalence above its stagnant level of 2 percent and a TPNIES approval would further support the goals of the ETC Model.

Response: We appreciate the commenters' input. We note that cost is not a consideration for TPNIES eligibility under § 413.236(b), and therefore is not relevant to our review of the Tablo® System's application. However, we believe that approval of the Tablo® System supports the goals of the ETC model by expanding beneficiary access to and retention of home HD.

Comment: The Tablo® System applicant commented on the CMS spending estimate of Medicare payment for additional home HD sessions, noting differences between its analysis and that of CMS but agreeing with CMS' estimates on spending for the fifth treatment. Several commenters stated that while existing guidance [110] allows for treatments more than three times per week when they are reasonable and necessary, coverage decisions are unrelated to the TPNIES eligibility determination. A commenter stated that the applicant provided no evidence regarding dialysis frequency for the population of patients that meet Medicare's clinical coverage criteria for additional treatments.

Response: We thank the commenters for their input and note that our CMS spending estimate of Medicare payment for additional home HD sessions that was included in the CY 2022 ESRD PPS proposed rule (86 FR 36339) was not part of our analysis of the TPNIES eligibility criteria in § 413.236(b). In addition, while Medicare clinical coverage criteria are beyond the scope of this rulemaking, we are not suggesting that the way in which ESRD facilities reflect home HD treatments on their claims would change due to our decision on the Tablo® System application.

Comment: We received several comments from health care professionals with experience in using the Tablo® System in a clinical setting, rather than a home setting. One commenter stated that the Tablo® System is a benefit for ESRD facilities with staffing shortages because less time will need to be spent with each patient. Several commenters shared their favorable experiences in using the Tablo® System in the hospital inpatient and intensive care unit settings and in treating COVID–19 patients. One commenter stated that 15 AKI inpatients with a mean age of 65 years were provided multiple Tablo® System treatments 3–6 times per week. The commenter further explained that the best urea reduction ratio achieved in the first 1–4 treatments, if available, was 41%; most treatments were successful and were slowed for hypotension or tachycardia; and some were aborted because of water pressure alarms signaling the need for filter replacement or clotted lines related to hypercoagulability among COVID–19 patients. The commenter further stated that most treatments were limited to 3–4 hours but up to 8 hours. Some commenters stated that patients treated with the Tablo® System in the hospital or ESRD facility setting gain familiarity and comfort with the device making it an easier transition to using the system at home.

Response: We thank the commenters for their input. Currently, the only capital-related assets not excluded from eligibility for the TPNIES under § 413.236(b)(6) are home dialysis machines used in the home for a single patient, as defined in § 413.236(a)(2). While these commenters' experiences with the Tablo® System do not involve its use in the home setting, we appreciate the additional input regarding the benefits of the Tablo® System.

After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are sufficient to demonstrate that the Tablo® System meets all of the eligibility criteria to qualify for the TPNIES for CY 2022. As a result, the Tablo® System will be paid for using a TPNIES per § 413.236(d).

III. Calendar Year (CY) 2022 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2022 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment

[110] Medicare Coverage Database. Retrieved May 24, 2021 from: *https://www.cms.gov/medicarecoverage-database/details/lcd-details.aspx?LCDId=35014&ver=39&NCDId=79&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=transplant&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAADgAAAAA&.*

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'' (86 FR 36322 through 36437), referred to as the ''CY 2022 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 9, 2021, with a comment period that ended on August 31, 2021. In that proposed rule, we proposed to update the AKI dialysis payment rate for CY 2022. We received 6 public comments on our proposal from large dialysis organizations, a non-profit dialysis association, a professional association, a provider advocacy organization, and a healthcare group.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2022 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2022

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual productivity-adjusted market basket payment update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this final rule, the CY 2022 ESRD PPS base rate is $257.90, which reflects the application of the CY 2022 wage index budget-neutrality adjustment factor of 0.99985 and the CY 2022 ESRDB market basket increase of 2.4 percent reduced by the productivity adjustment of 0.5 percentage point, that is, 1.9 percent. Accordingly, we are finalizing a CY 2022 per treatment payment rate of $257.90 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index, as discussed in the next section of this final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this final rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated previously, we are finalizing a CY 2022 AKI dialysis payment rate of $257.90, adjusted by the ESRD facility's wage index.

The comments and our responses to the comments on our AKI dialysis payment proposal are set forth below.

Comment: Several commenters, including a large dialysis organization and a professional association, commented in support of the proposed update to the AKI dialysis payment rate for CY 2022. They also expressed support for using the same methodology as in previous years for the AKI update. A large dialysis organization expressed specific appreciation for the detailed explanation of the CMS process and methodology to develop the AKI payment amount that has been included in prior rules. This organization noted that CMS has recognized that treatment for AKI differs from treatment for ESRD. The organization stated that although the services provided to AKI patients may be the same, their frequency may exceed those typically required by patients with ESRD. The organization also noted that in the CY 2017 ESRD PPS final rule, CMS indicated that it planned to make available public use files on utilization of services by AKI patients once the agency had compiled one full year of claims. The organization stated that CMS subsequently reported that the agency would continue to monitor utilization trends of items and services furnished to individuals with AKI. Along with other commenters, the large dialysis organization supports the data collection effort and CMS's commitment to ensure a data-driven approach to developing methodological changes to the AKI's rate development. The commenters urged CMS to share its monitoring plans to allow the public to better understand the specific data elements that CMS is collecting and analyzing.

Response: We appreciate the comments in support of the AKI payment rate update. As the commenter stated, we have been monitoring the trends of AKI beneficiaries in ESRD facilities and acute inpatient hemodialysis. This has included quantification of drugs, laboratory tests and other services provided on acute inpatient dialysis claims. We also examine other diagnoses recorded before an acute inpatient dialysis claim.

During the TEP held in December 2020, we reviewed dialysis-related costs, resource utilization and characteristics of the AKI–D (outpatient dialysis for patients with AKI) population beginning January 1, 2017, when their outpatient dialysis treatment first became eligible under the ESRD PPS claims. That report can be found at the following link: *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.* As we continue to analyze costs, utilization and patient characteristics, we will also examine data as it relates to an additional site of service for AKI patients. We will also incorporate additional data monitoring for COVID–19 patients who have experienced AKI. The results of the data analysis will be shared in the future in public use files on the ESRD PPS website.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2022 ESRD PPS base rate is $257.90. Accordingly, we are finalizing a CY 2022 payment rate of $257.90 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030),
- CY 2012 ESRD PPS final rule (76 FR 628),
- CY 2012 ESRD PPS final rule (76 FR 70228),
- CY 2013 ESRD PPS final rule (77 FR 67450),
- CY 2014 ESRD PPS final rule (78 FR 72156),
- CY 2015 ESRD PPS final rule (79 FR 66120),
- CY 2016 ESRD PPS final rule (80 FR 68968),

- CY 2017 ESRD PPS final rule (81 FR 77834),
- CY 2018 ESRD PPS final rule (82 FR 50738),
- CY 2019 ESRD PPS final rule (83 FR 56922),
- CY 2020 ESRD PPS final rule (84 FR 60648), and
- CY 2021 ESRD PPS final rule (85 FR 71398).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Extraordinary Circumstances Exception (ECE) Previously Granted for the ESRD QIP Including Notification of ECE Due to ESRD Quality Reporting System Issues

1. Extraordinary Circumstance Exception (ECE) Previously Granted in Response to the COVID–19 PHE

On March 22, 2020, in response to the COVID–19 PHE, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs.[111] On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and value-based purchasing (VBP) program.[112] Each of these ECEs relieved these providers and facilities of their obligation to report data for Q4 CY 2019, Q1 and Q2 CY 2020, but we stated that we would score such data if optionally reported.

The September 2020 IFC updated the ECE we granted in response to the COVID–19 PHE for the ESRD QIP and several other quality reporting programs (85 FR 54827 through 54838).

In the IFC, we updated the ECE policy for the ESRD QIP (85 FR 54828 through 54830). First, we updated our regulations at § 413.178(d)(7) to state that a facility has opted out of the ECE for COVID–19 with respect to the reporting of Q4 CY 2019 NHSN data if the facility actually reported the data by the March 31, 2020 deadline but did not notify CMS that it would do so. Additionally, we finalized that facilities would not have the option to opt-out of the ECE we granted with respect to Q1 and Q2 2020 ESRD QIP data. We stated that measures calculated using excepted data could affect the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19, and therefore may not provide a nationally comparable assessment of performance in keeping with the program goal of national comparison.

In the September 2020 IFC, we welcomed public comments on our policy to update our regulations at § 413.178(d)(7) to consider a facility as having opted out of the ECE with respect to NHSN data reported for Q4 2019 if the facility actually reported the data by the submission deadline, without notifying CMS, and on the exception we finalized to the ECE opt out policy for the ESRD QIP to exclude any ESRD QIP data that facilities optionally reported during Q1 and Q2 2020 from our calculation of PY 2022 TPSs and from the baseline for PY 2023. The comments we received on these policies and our responses are set forth below.

Comment: Several commenters supported CMS' updated application of the ECE granted in response to the PHE due to COVID–19. A few commenters also agreed with CMS' concerns regarding the national comparability of data from Q1 and Q2 of CY 2020 and noted that the integrity and validity of any measurement calculations associated with these data could be compromised.

Response: We thank commenters for their support.

Comment: A few commenters expressed strong concern that the data collected under the ESRD QIP will not adequately reflect the quality of care provided due to the impact of COVID–19 and the shortened data collection period. A few commenters noted that the data collected under the ESRD QIP for 2020 will be limited due to the COVID–19 PHE and the nationwide ECE excluding Q1 and Q2 data from consideration, and will undermine the reliability of measure results for scoring purposes. A few commenters recommended that CMS suspend penalties and payment adjustments for the 2020 performance year, expressing concern that the data collected under the ESRD QIP will not adequately reflect the quality of care provided due to the impact of the COVID–19 PHE and the nationwide ECE.

Response: We share commenters' concerns regarding the potential impact on ESRD QIP measure calculations for PY 2022 due to the COVID–19 PHE and the shortened data collection period resulting from the nationwide ECE. In order to avoid unfairly penalizing facilities based on data that may not accurately reflect the quality of care provided due to circumstances beyond their control, in section IV.D of this final rule we are finalizing our proposal to adopt a special scoring and payment policy for PY 2022, under which we will not score or apply payment reductions to any ESRD facilities for PY 2022 under the ESRD QIP.

Comment: A few commenters expressed strong support for extending the ECE through the end of 2020, noting the continuing impact of COVID–19 on dialysis facilities. A few commenters also noted that COVID–19 case rates were higher in Q3 and Q4 of 2020 for patients attributed to dialysis facilities in certain geographic regions, and that these higher case rates may have affected performance scores under ESRD QIP.

Response: We agree that the impact of COVID–19 on dialysis facilities in 2020 has affected our ability to accurately measure their performance. We resumed data collection for the ESRD QIP on July 1, 2020 because we believe that collecting ESRD QIP measure data is important in order to better understand the impact of COVID–19 on the data as it relates to factors such as the changing geographic differences in COVID–19 incidence and the quality of ESRD care provided to Medicare beneficiaries. However, to avoid unfairly penalizing facilities based on data that may not accurately reflect their quality of care, we are finalizing a measure suppression policy for the duration of the COVID–19 PHE and a special scoring and payment policy for PY 2022 in sections IV.C. and IV.D. of this final rule.

Comment: One commenter expressed support for CMS' intention to provide subregulatory notice of decisions surrounding payment adjustments and penalties under the ESRD QIP.

Response: In the September 2020 IFC, we stated that in the interest of time and transparency, we may provide subregulatory advance notice of our intentions regarding payment adjustments and penalties (85 FR 54830). However, we would like to clarify that we would use rulemaking to propose any actual modifications to the ESRD QIP scoring and payment adjustment methodologies and that we

[111] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[112] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

are using this final rule to finalize our scoring and payment adjustment policy for PY 2022.

Comment: One commenter requested that CMS provide further guidance to facilities regarding the criteria for requesting an ECE during a pandemic.

Response: The criteria for requesting an ECE under the ESRD QIP during a pandemic are the same as the criteria for requesting an ECE under the ESRD QIP due to other extraordinary circumstances beyond a facility's control. These requirements can be found in our regulations at 42 CFR 413.178(d)(3) through (7). Under these requirements, a facility may request an ECE within 90 days of the extraordinary circumstance occurring and must submit an ECE request form to CMS with the following information:

(i) Facility CCN.

(ii) Facility name.

(iii) CEO name and contact information.

(iv) Additional contact name and contact information.

(v) Reason for requesting an exception.

(vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

In certain circumstances, such as a determination that an extraordinary circumstance has occurred that affects an entire region or locale, CMS may grant exceptions to facilities without a request. We note that facilities may also reject an ECE granted by CMS under certain circumstances. Technical details can be viewed on the QualityNet website.[113]

As established in the September 2020 IFC, we have finalized our updated application of the ECE granted in response to the COVID–19 PHE.

2. ECE Due to ESRD Quality Reporting System (EQRS) Issues

On November 9, 2020,[114] we launched the ESRD Quality Reporting System (EQRS). The EQRS contains the functionalities of the following three legacy ESRD Systems in one global application: (1) A quality measure and VBP performance score review system (ESRD QIP System); (2) an ESRD patient registry and quality measure reporting system through the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb); and (3) Medicare coverage determination support through the Renal Management Information System (REMIS). The transition to EQRS supports our efforts to consolidate the functionalities of the CROWNWeb, ESRD QIP System, and REMIS applications into a single system, and aims to provide ongoing support to the ESRD user community to foster accurate and timely monthly data submission. This migration eliminates the need for multiple user accounts, and will in the long-term also improve the overall user experience and reduce burden due to enhanced navigation features.

In order to access EQRS, all authorized users must create an account with the Health Care Quality Information Systems (HCQIS) Access Roles and Profile, known as HARP, which is a secure identity management portal provided by CMS. Previously, users created separate accounts for each ESRD application through CMS' Enterprise Identity Data Management (EIDM) system. Creating an account via HARP provides users with a user ID and password that can be used to access many CMS applications. It also provides a single location for users to modify their profile, change their password, update their challenge question, and add or remove two-factor authentication devices. Users can register for a HARP account by going to the QualityNet HARP Registration page, available at *https://harp.cms.gov/register/profile-info*.

We stated in the CY 2022 ESRD PPS proposed rule (86 FR 36348) that since the launch of EQRS, several critical data submission issues had been identified that impact the overall quality and accuracy of data available to support the implementation of the ESRD QIP, and we suspended all clinical data submissions into EQRS to allow time to resolve the issue.[115] Based on our assessment, the data submission issues only impacted ESRD QIP, Dialysis Star Ratings, Dialysis Facility Compare and data submitted for ESRD Network quality improvement activities. In the proposed rule, we noted that we had analyzed the data submission issues and stated our belief that the data systems issues would be resolved on or about July 12, 2021.[116]

We recognized that these operational systems issues would prevent facilities from submitting ESRD QIP clinical data until the data systems issues were resolved. Therefore, we announced a blanket extension of remaining CY 2020 clinical reporting deadlines (86 FR 36348 through 36349). Under this extension, facilities would have until September 1, 2021 to submit September through December 2020 ESRD QIP clinical data. In the proposed rule (86 FR 36348), we stated our belief that this reporting extension aligned with the time estimated for resolution of our operational systems issues and would give dialysis facilities nearly 7 weeks to submit their data to EQRS. We stated that we would provide further details to facilities when the EQRS issues were resolved, as well as when facilities could begin submitting their data for CY 2020 and CY 2021, through routine communication channels to facilities, vendors, Quality Improvement Organizations (QIOs) and ESRD Networks. We stated that the communications could include memos, emails, and notices on the public QualityNet website (*https://www.qualitynet.org/*). As this situation was ongoing at the time, we stated in the proposed rule that we would announce any relevant extension deadlines and data submission requirements for impacted CY 2021 data through the routine communication channels discussed above. On September 3, 2021, we announced that the September 1, 2021 data submission deadline for September-December 2020 clinical data had been extended to September 15, 2021 in order to give facilities additional time to submit their data.[117]

Because the current data submissions issue would not be resolved until or about July 12, 2021 and had impacted all facilities that participate in ESRD QIP, we stated our belief that granting a blanket ECE to all facilities without a request under 42 CFR 413.178(d)(6)(ii) was the appropriate remedy under these circumstances. We also stated our belief that requiring facilities to report the CY 2020 data impacted by this ECE by September 1, 2021 was reasonable. In our data suspension announcements, we noted that facilities were expected to continue to use EQRS to collect clinical data to complete tasks such as admit and discharge patients, complete CMS

[113] *https://qualitynet.cms.gov/esrd/esrdqip/participation#tab5.*

[114] *https://mycrownweb.org/2020/11/november-2020-newsletter/.*

[115] *https://mycrownweb.org/2021/02/eqrs-data-reporting-update-feb-2021/.*

[116] On July 9, 2021, we announced that the EQRS data suspension will be concluded as of July 12, 2021, and that EQRS testing had been performed to ensure that the system is working as expected. *https://mycrownweb.org/2021/07/eqrs-data-reporting-to-resume/.*

[117] *https://mycrownweb.org/2021/09/clarified-eqrs-2020-data-submission-deadline-extension-2021-clinical-data-submission-deadline/.* We also have provided additional information at: *https://mycrownweb.org/wp-content/uploads/2021/07/FAQ_Resuming-2020_2021Clinical-Data-Submission_Final_508.pdf.*

forms (such as the CMS–2728: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration, CMS–2744: End Stage Renal Disease Annual Facility Survey Form, and CMS–2746: ESRD Death Notification), add or update treatment summaries, resolve notifications within a timely manner, and should also continue to keep facilities' information up-to-date.[118] In other words, although facilities were unable to submit clinical data through EQRS, facilities were advised that they must continue to collect the clinical data.

In the proposed rule (86 FR 36349), we stated that while we were working to resolve all known systems issues by July 12, 2021 and reopen submissions so that facilities may submit their September through December 2020 ESRD QIP data no later than September 1, 2021, we would only be able to ensure the validity of the impacted data after they are submitted. Given that the system issues experienced during the initial implementation of the EQRS, if not fully resolved, could potentially impact the accuracy and reliability of the data reported, we were concerned that facilities may be unfairly penalized because the current systems issues may impact the quality of the data. The EQRS system issues had resulted in multiple or incorrect dates of patient admissions and/or discharges, as well as showing duplicate patient records. Facilities had also expressed concerns about their experience with EQRS issues, noting that there was no way for a facility to verify accuracy or completeness. They had reported issues including missing record status in response files, which meant that facilities did not know if the records were accepted or received an error response, and issues with determining whether clinical data were accepted because the information did not show in the user interface or the reports that facilities were receiving from EQRS.

We stated in the proposed rule that we recognized stakeholders' concerns about the potential impact to the quality of data for CY 2020. We stated our belief that the observed system issues, and any unresolved issues that may be identified only after data submissions are resumed, could impact the quality and accuracy of the data needed to calculate accurate ESRD QIP scores used for PY 2022 ESRD QIP calculations because patient admittance dates, discharge dates, record status in response files, clinical data, and the number of active patient cases are data points that are included in measure calculations for all of the PY 2022 ESRD QIP measures. If these data points were incorrect, then this would impact our ability to accurately calculate measures and would distort a facility's measure performance.

Therefore, because of the EQRS system issues described above, and additionally, due to the impact of the COVID–19 PHE on some of the PY 2022 ESRD QIP measures, as described more fully in section IV.C. of this final rule, we proposed to not score or award a TPS to any facility, or reduce payment to any facility, in PY 2022. As discussed more fully in section IV.D below, we are finalizing that proposal in this final rule.

Although we considered if there may be any alternative data sources for the measures impacted by these EQRS system issues, we concluded that this was not feasible for several reasons. First, all 14 ESRD QIP measures for PY 2022 were impacted by these system issues. Although certain measures do not require that facilities submit clinical data into EQRS, we use EQRS data to determine whether a facility has treated a sufficient number of patients in order to meet the measure's minimum patient case threshold necessary to calculate the measure for ESRD QIP. For example, the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure requires that facilities report data to NHSN. However, the measure also has a requirement to exclude facilities that do not treat at least 11 eligible in-center hemodialysis patients during the 12 month performance period. In order to determine whether a facility has treated at least 11 eligible patients, we use EQRS admission data and Medicare claims data in order to determine whether the facility is eligible to receive a score on the measure.[119]

We ultimately decided to propose the special rule for PY 2022, as described further, because not only do these system issues impact all ESRD QIP measures, which could lead to distorted performance scores and unfair penalties, but we also wanted to provide facilities with the business certainty they need regarding their PY 2022 payments. In order to determine whether all data quality issues have been resolved when EQRS reopens for data submissions, we stated that we would need time to validate the impacted data after facilities are able to resume data submission. Due to the timing of this reporting extension, we stated our belief that there were no feasible alternative data sources for PY 2022. Therefore, we stated that the scoring and payment modifications we proposed for PY 2022 were appropriate in this situation.

Comment: Several commenters expressed appreciation and support for the reporting extension granted due to EQRS issues. A few commenters noted that facilities have experienced challenges with reporting data to EQRS and that the extension is helpful particularly as facilities continue to also address the impact of the COVID–19 PHE.

Response: We thank the commenters for their support.

Comment: A few commenters requested that CMS extend the reporting extension to the end of CY 2021, noting the ongoing COVID–19 PHE and continued challenges with data reporting. One commenter expressed the belief that extending the reporting deadline to the end of CY 2021 will help to ensure the accuracy and completeness of the data submitted. One commenter expressed concern that EQRS issues may not be fully resolved by the anticipated deadline, and requested that CMS issue further flexibilities if necessary.

Response: Although we initially extended the data submission deadline to September 1, 2021, we subsequently extended that deadline to September 15, 2021 in order to give facilities additional time to submit their data. We note that all outstanding EQRS issues have been resolved and we reopened access to EQRS on July 12, 2021. We believe that 2 months was sufficient time for facilities to report September through December 2020 ESRD QIP data.

Comment: A few commenters expressed support for the issuance of notifications through routine communication channels, in the event that an additional extension is granted due to unresolved EQRS issues.

Response: We thank the commenters for their support.

C. Flexibilities for the ESRD QIP in Response to the COVID–19 PHE

1. Adoption of a Measure Suppression Policy for the Duration of the COVID–19 PHE

In the CY 2022 ESRD PPS proposed rule, we stated that in previous rules, we have identified the need for flexibility in our quality measurement programs to account for changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our

[118] *https://mycrownweb.org/2021/02/eqrs-data-reporting-update-feb-2021/.*

[119] *https://www.cms.gov/files/document/cy-2021-final-technical-specifications-20201130.pdf.*

programs are not affected negatively when their quality performance suffers for reasons not due to the care provided, but instead due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 PHE, which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE have impeded effective quality measurement in many ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. Measures used in the ESRD QIP need to be evaluated to determine whether their specifications need to be updated to account for new clinical guidelines, diagnosis or procedure codes, and medication changes that we have observed during the PHE. Additionally, because COVID–19 prevalence is not consistent across the country, dialysis facilities located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we stated in the proposed rule that we remain significantly concerned that the ESRD QIP's quality measure scores that are calculated using data submitted during the PHE for COVID–19 will be distorted and will result in skewed payment incentives and inequitable payments, particularly for dialysis facilities that have treated more COVID–19 patients than others.

We further stated that it is not our intention to penalize dialysis facilities based on measure scores that we believe are distorted by the COVID–19 pandemic and, thus, not reflective of the quality of care that the measures in the ESRD QIP were designed to assess. As previously discussed, the COVID–19 pandemic has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those made on clinical topics covered by the ESRD QIP's measures. As a result of the COVID–19 PHE, dialysis facilities could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, payment penalties in the ESRD QIP. We also stated that we are concerned that regional differences in COVID–19 prevalence during the performance period for PY 2022 have directly affected dialysis facilities' measure scores on the ESRD QIP for PY 2022. Although these regional differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by dialysis facilities, they could directly affect the payment penalties that these facilities could receive and could result in an unfair and inequitable distribution of those penalties. These inequities could be especially pronounced for dialysis facilities that have treated a large number of COVID–19 patients.

We therefore proposed to adopt a policy for the duration of the COVID–19 PHE that would enable us to suppress the use of ESRD QIP measure data for all facilities if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the resulting total performance scores (TPSs) significantly (86 FR 36350). We also proposed to suppress certain measures for the PY 2022 program year because we have determined that circumstances caused by the COVID–19 PHE have affected those measures significantly. In addition, due to both the impacts of the COVID–19 PHE on certain measures and the EQRS system issues described in section IV.B.2. we proposed to adopt a special scoring and payment rule for PY 2022, as described more fully in section IV.D.

In developing the proposed policy, we considered what circumstances caused by the COVID–19 PHE would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing (VBP) program. We stated our belief that a significant deviation in measured performance that can be reasonably attributed to the COVID–19 PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we stated our belief that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 pandemic, we stated our belief that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also noted that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we stated our belief that, as evidenced during the COVID–19 pandemic, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress ESRD QIP measures for one or more payment years that overlap with the COVID–19 PHE. We proposed to adopt these Measure Suppression Factors for use in the ESRD QIP and, for consistency, the following other VBP programs: Hospital VBP Program, Hospital Readmissions Reduction Program, Hospital-Acquired Condition (HAC) Reduction Program, and Skilled Nursing Facility VBP Program (see, for example, 86 FR 25460 through 25462, 25470 through 25472, and 25497 through 25499). We stated our belief that these Measure Suppression Factors will help us evaluate measures in the ESRD QIP and that their adoption in the other VBP programs noted previously will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are as follows:

- *Factor 1:* Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- *Factor 2:* Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE.
- *Factor 3:* Rapid or unprecedented changes in:
  - ++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
  - ++ the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
- Factor 4: Significant national shortages or rapid or unprecedented changes in:
  - ++ Healthcare personnel;
  - ++ medical supplies, equipment, or diagnostic tools or materials; or
  - ++ patient case volumes or facility-level case mix.

In the CY 2022 ESRD PPS proposed rule, we also considered alternatives to this proposed policy that could fulfill our objective to not penalize dialysis facilities for measure results that are distorted due to the COVID–19 PHE. As previously noted, the country continues to grapple with the effects of the COVID–19 pandemic, and in March

2020, CMS issued a nationwide, blanket Extraordinary Circumstances Exception (ECE) for all hospitals and other facilities participating in our quality reporting and VBP programs in response to the COVID–19 PHE. This blanket ECE excepted all data reporting requirements for Q1 and Q2 2020 data, including claims data and data collected through the CDC's web-based surveillance system for this data period, and quality data collection resumed on July 1, 2020. For claims-based measures, we also stated that we would exclude all qualifying Q1 and Q2 2020 claims from our measure calculations. We considered extending this blanket ECE that we issued for Q1 and Q2 2020 to also include Q3 and Q4 2020. This alternative would have protected providers and suppliers from having their quality data used for quality scoring purposes if those data were likely to have been affected significantly by the COVID–19 PHE. However, this option would have made quality data collection and reporting to CMS no longer mandatory and would have left us with no comprehensive data available to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

As an alternative to the proposed quality measure suppression policy, we also considered not suppressing any measures under the ESRD QIP. However, this alternative would mean assessing dialysis facilities using quality measure data that has been significantly affected by the COVID–19 pandemic. Additionally, given the geographic disparities in the COVID–19 pandemic's effects, we stated in the proposed rule that implementation of the PY 2022 ESRD QIP as previously finalized would place dialysis facilities in regions that were more heavily impacted by the pandemic in Q3 and Q4 of 2020 at a disadvantage compared to facilities in regions that were more heavily impacted during the first two quarters for CY 2020 (86 FR 36350 through 36351).

We stated in the proposed rule that we viewed this measure suppression proposal as a necessity to ensure that the ESRD QIP does not penalize facilities based on external factors that were beyond the control of facilities. We intended for this proposed policy to provide short-term relief to dialysis facilities when we have determined that one or more of the Measure Suppression Factors warrants the suppression of an ESRD QIP measure.

We welcomed public comments on this proposal for the adoption of a measure suppression policy for the duration of the COVID–19 PHE, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for the measure suppression policy for the duration of the COVID–19 PHE. Several commenters expressed appreciation that the proposed measure suppression policy would help to address the ongoing challenges of the COVID–19 PHE. Several commenters expressed support for the proposed measure suppression policy, noting that measure scores may be distorted due to the substantial impact of the COVID–19 PHE on facility performance and that such a policy would help to avoid penalizing facilities based on potentially distorted data due to the COVID–19 PHE.

Response: We thank commenters for their support.

Comment: One commenter acknowledged the benefit of the proposed measure suppression policy, but also expressed concern regarding the exclusion of data showing the high morbidity and mortality of ESRD patients with COVID–19.

Response: Although we will not score facilities using data submitted during the ECE, we do intend to make individual facility data that was reported available to that facility so that the facility has an opportunity assess the impact of COVID–19 on its ESRD patients. We will also publicly report the measure rates with appropriate caveats. We believe that providing as much information as possible to facilities in this way while also publicly reporting performance data to the public with appropriate caveats balances fairness in our value-based purchasing programs with the public's need for transparency.

Comment: Several commenters expressed support for the proposals to address the negative impact of the pandemic on the ESRD QIP and recommended that CMS consider similar considerations for CY 2021 measure data. A few commenters strongly recommended that CMS consider extending relief under the ESRD QIP to PY 2023, citing the rise of the Delta variant and continuing impact of COVID–19 on facilities as well as the healthcare system nationwide. These commenters noted the continuing impact of the PHE on ESRD QIP measures, due both to the impact of COVID–19 on ESRD patients which may result in new hospital admissions and impact facility performance on SHR and SRR measures, as well as the strain on the healthcare system due to the influx of COVID–19 patients which may impact the availability of vascular access procedures and transplant evaluations. A few commenters noted that geographic variations in the COVID–19 PHE during CY 2021 continue to exacerbate distortions in ESRD QIP measure performance.

Response: The measure suppression policy that we are finalizing in this final rule applies for the duration of the COVID–19 PHE. We will continue to monitor the impact of the COVID–19 PHE on dialysis facilities, and we would consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

Comment: Several commenters expressed support for the proposed Measure Suppression Factors. Several commenters noted that they will help to mitigate the negative impact of the challenges presented by the COVID–19 PHE such as significant deviation in national performance, the distorting impact on measures themselves, changing guidelines and protocols related to the PHE, and challenges due to shortages in both medical supplies, staffing, and patient volume and case-mix on quality measures. One commenter expressed support for the proposed Measure Suppression Factors, noting that they will help to ensure consistency in measure evaluation and suppression.

Response: We thank commenters for their support.

Comment: A few commenters expressed concern regarding the proposed Measure Suppression Factors. One commenter expressed concern that proposed Measure Suppression Factor 2 may overlook indirect or downstream clinical impacts that may not be considered ''proximate,'' noting for example the impact of the COVID–19 PHE shutdown on non-urgent scheduled vascular placement procedures leading to reduced catheter insertions and fistula rates as well as a delay in patient follow up regarding such procedures due to patient fears of COVID–19 exposure. One commenter expressed concern that proposed Measure Suppression Factor 4 does not sufficiently address regional or State-by-State impacts on personnel, patient volumes or case-mix, and medical

supplies or equipment, and recommended that CMS broaden application of its scope to include sub-national, regional, and State impacts. One commenter recommended that CMS consider under Measure Suppression Factor 4 the impact of healthcare personnel shortages on ESRD facilities as a result of the COVID–19 PHE. One commenter recommended that CMS consider including under Measure Suppression Factor 4 circumstances where there is a statistically meaningful lower denominator from prior years due to factors outside of a facility's control, such as changes in demographics.

Response: We developed the Measure Suppression Factors based on several considerations specifically related to the PHE for COVID–19, including national, regional, and State impacts. For example, we note that Measure Suppression Factor 4 addresses healthcare shortages in personnel as well as patient volumes and facility-level case mix. We believe the Measure Suppression Factors we are adopting for the COVID–19 PHE are sufficient to guide us in identifying whether circumstances caused by the COVID–19 PHE have affected ESRD QIP measures and the resulting TPSs.

Comment: One commenter recommended adding an additional measure suppression factor to suppress a measure in cases where the measure denominator is statistically meaningfully lower due to circumstances beyond the facility's control such as COVID–19 mortality, noting that this may significantly also impact measure performance.

Response: We believe that the commenter's suggestion would be captured by the proposed Measure Suppression Factor 4. As we discussed in the proposed rule (86 FR 36350), we developed these suppression factors to assess changing conditions due to the COVID–19 PHE and proposed them consistently in several of our value-based purchasing programs. As we stated above, we believe the Measure Suppression Factors we are adopting for the COVID–19 PHE are sufficient to guide us in identifying whether circumstances caused by the COVID–19 PHE have affected ESRD QIP measures and the resulting TPSs.

Comment: A few commenters expressed support for the proposal to provide confidential feedback reports to dialysis facilities under the proposed measure suppression policy, noting that it will allow facilities to focus on performance improvement and also allow CMS to track developments in the field.

Response: We thank the commenters for their support and note that we are finalizing this proposal in this final rule.

Comment: One commenter expressed support for the public reporting of performance scores from CY 2020 with appropriate caveats.

Response: We thank the commenter for its support.

Comment: A few commenters did not support the public reporting of suppressed measures, noting reliability concerns due to the impact of the COVID–19 PHE on measure data.

Response: We believe it is important to balance fairness with the public's need for transparency. Therefore, we intend to make the data publicly available. In order to address concerns about publicly reporting data that was collected by facilities during the COVID–19 PHE, we will appropriately caveat the publicly displayed data for suppressed measures to note that the measures have been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. We believe these caveats will mitigate any public confusion that could otherwise result from the display.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt a measure suppression policy for the duration of the COVID–19 PHE. We are also finalizing the proposed Measure Suppression Factors that we proposed for purposes of this measure suppression policy. We will also publicly report the data with appropriate caveats.

2. Suppression of Four ESRD QIP Measures for PY 2022

a. Background

In response to the PHE for COVID–19, we conducted analyses of the 14 current ESRD QIP measures to determine whether and how COVID–19 may have impacted the validity of these measures. For the reasons discussed in the CY 2022 ESRD PPS proposed rule, we concluded that COVID–19 has so severely impacted the validity of four measures that we believe we cannot fairly and equitably score these measures for the PY 2022 program year. Accordingly, we proposed to suppress these measures for the PY 2022 program year for all ESRD QIP participants (86 FR 36351). Specifically, the measures we proposed to suppress for the PY 2022 ESRD QIP are as follows:

- SHR clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:
  ++ healthcare personnel;
  ++ medical supplies, equipment, or diagnostic tools or materials; or
  ++ patient case volumes or facility-level case mix);
- Standardized Readmission Ratio (SRR) clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:
  ++ healthcare personnel;
  ++ medical supplies, equipment, or diagnostic tools or materials; or
  ++ patient case volumes or facility-level case mix);
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years); and
- Long-Term Catheter Rate clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years).

We received comments on additional measures that we should consider suppressing and address them below.

Comment: Several commenters recommended that we suppress the Standardized Fistula Rate measure. A few commenters noted that the Standardized Fistula Rate measure and the Long-Term Catheter Rate measure are both Hemodialysis Vascular Access measures, but only the Long-Term Catheter Rate measure is proposed for suppression. A few commenters noted that AV fistula placements may have been delayed because it was not clear whether such procedures were considered an ''elective surgery'' in the beginning of the PHE and also because

ESRD patients may have delayed or avoided medical treatments because of COVID–19 concerns. Several commenters recommended that CMS suppress the Percentage of Prevalent Patients Waitlisted (PPPW) measure, noting that the COVID–19 PHE had a significant negative impact on transplant surgeries, referrals and waitlists, as well as other related areas. A few commenters also noted that waitlist additions significantly decreased during the COVID–19 PHE.

A few commenters recommended that CMS consider suppressing the Kt/V Dialysis Adequacy measure, noting that the impact of the COVID–19 PHE on catheter rates has a corresponding impact on the Kt/V measure, as patients with catheters will have lower Kt/V rates. One commenter recommended suppressing the Kt/V Dialysis Adequacy measure under proposed Measure Suppression Factor 1, due to significant deviation in national measure performance. One commenter recommended that CMS suppress the NHSN BSI clinical measure under Measure Suppression Factor 3 and Factor 4, noting that challenges in care delivery and treatment related to catheter removal and AVF insertion resulted in an increased likelihood of patient infection, as well as an increase in patient volume and case-mix due to COVID–19 patients developing AKI and requiring catheterization.

Response: At the time of the proposed rule, there was not sufficient data to determine whether suppression was appropriate for the Standardized Fistula Rate measure, the PPPW measure, the Kt/V Dialysis Adequacy measure, or the NHSN BSI clinical measure. We note that the status of the data remains unchanged since the proposed rule was published. Although we agree with commenters that performance on the Standardized Fistula Rate measure is linked to measure performance on the Long-Term Catheter Rate measure, the data that was available at the time of the proposed rule indicated that the COVID–19 PHE had a comparatively lower impact on the Standardized Fistula Rate measure.

For the PPPW measure, our analysis of the relevant data available at the time of the proposed rule indicated temporal declines in waitlist removal among prevalent patients and similarly a decline in waitlisting and transplants in incident ESRD patients in March 2020 through May 2020 compared to prior years. However, we also observed that trends generally returned to normal starting in June and July 2020 and reflected data similar to prior years.

Although performance on the Kt/V Dialysis Adequacy measure deviated temporarily, our analysis indicated that Kt/V rates stabilized shortly thereafter and reflect measure performance similar to prior years. Based on our analysis, Kt/V rates in CY 2020 were similar to rates in CY 2019 until April, where they dropped by an average of 0.4 percent. However, beginning in June 2020, Kt/V rates were the same as or higher than national average rates in March 2020.

We were unable to assess the impact of the COVID–19 PHE on the NHSN BSI clinical measure, which requires a full 12 months of data in order to calculate measure performance. The CDC will not be able to calculate measure performance for the NHSN BSI clinical measure because the nationwide ECE granted in response to the COVID–19 PHE excepted data from Q1 and Q2 of CY 2020. As a result, facilities will not receive scores for the NHSN BSI clinical measure. We also note that suppressing the NHSN BSI clinical measure would be unlikely under Measure Suppression Factor 3 and Factor 4, as the links between those factors and the impacts on measure performance cited by the commenter are not sufficiently direct. Although challenges in care delivery and treatment related to catheter removal and AVF insertion resulted in an increased likelihood of patient infection, as well as an increase in patient volume and case-mix due to COVID–19 patients developing AKI and requiring catheterization, neither of those directly caused patients to develop more bloodstream infections as a result of the COVID–19 PHE.

However, we will continue to monitor and review the data and consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

b. Suppression of the SHR clinical measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36351 through 36352), we proposed to suppress the SHR clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. The SHR clinical measure is an all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate. The intent of the SHR clinical measure is to improve health care delivery and care coordination to help reduce unplanned hospitalization among ESRD patients.

Based on our analysis of Medicare dialysis patient data from January 2020 through August 2020, we found that hospitalizations involving patients diagnosed with COVID–19 resulted in higher mortality rates, higher rates of discharge to hospice or skilled nursing facilities, and lower rates of discharge to home than hospitalizations involving patients who were not diagnosed with COVID–19. Specifically, the hospitalization rate for Medicare dialysis patients diagnosed with COVID–19 was more than 7 times greater than the hospitalization rate during the same period for Medicare dialysis patients who were not diagnosed with COVID–19, which is much greater than the relative risk of hospitalization for any other comorbidity. In the proposed rule (86 FR 36351), we stated that this indicates that COVID–19 has had a significant impact on the hospitalization rate for dialysis patients. Because COVID–19 Medicare dialysis patients are at significantly greater risk of hospitalization, and the SHR clinical measure was not developed to account for the impact of COVID–19 on this patient population, we expressed our concern about the effects of the observed COVID–19 hospitalizations on the SHR clinical measure. We also noted that COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. Because of the increased hospitalization risk associated with COVID–19 and the Medicare dialysis patient population, we expressed our concern that these regional differences in COVID–19 rates have led to distorted hospitalization rates such that we could not reliably measure national performance on the SHR clinical measure.

Our analysis of the available Medicare claims data indicated that the COVID–19 PHE has had significant effects on hospital admissions of dialysis patients,

and would result in significant deviation in national performance on the measure during the COVID–19 PHE which could be significantly worse as compared to historical performance during the immediately preceding program years. Not only are there effects on patients diagnosed with COVID–19, but the presence of the virus strongly affected hospital admission patterns of dialysis patients from March 2020 to June 2020, and we expressed our concern that similar effects would be seen in the balance of the calendar year (CY) as the PHE continued. Because the COVID–19 pandemic swept through geographic regions of the country unevenly, we expressed our concern that dialysis facilities in different regions of the country would have been affected differently throughout the 2020 year, thereby skewing measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. Given the limitations of the data available to us for CY 2020, we stated our belief the resulting performance measurement on the SHR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP.

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the SHR clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the COVID–19 PHE affected measure performance on the current SHR clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we stated that we would continue to collect the measure's claims data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

In the proposed rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SHR clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the SHR clinical measure as additional data become available. As an alternative, we considered whether we could exclude patients with a diagnosis of COVID–19 from the SHR clinical measure cohort, but we determined suppression will provide us with additional time and additional months of data potentially impacted by COVID–19 to more thoroughly evaluate a broader range of alternatives. We want to ensure that the measure reflects care provided to Medicare dialysis patients and we are concerned that excluding otherwise eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across facilities and hospitals over time. As an alternative approach, we stated that we also might consider updating the specifications for the SHR clinical measure to eliminate any exposure time and events after infection for patients who contract COVID–19, as COVID–19 symptoms may continue to affect patients after infection. We stated our belief that this approach might help distinguish between ESRD-related hospitalizations and COVID–19 related hospitalizations that might otherwise impact SHR clinical measure calculations.

We welcomed public comment on our proposal to suppress the SHR clinical measure for PY 2022. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the SHR clinical measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SHR clinical measure for PY 2022.

c. Suppression of the SRR Clinical Measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36352 through 36353), we proposed to suppress the SRR clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. The SRR assesses the number of readmission events for the patients at a facility, relative to the number of readmission events that would be expected based on overall national rates and the characteristics of the patients at that facility as well as the number of discharges. The intent of the SRR clinical measure is to improve care coordination between dialysis facilities and hospitals to improve communication prior to and post discharge.

Based on our analysis, we found that index discharge hospitalizations involving dialysis patients diagnosed with COVID–19 resulted in lower readmissions and higher mortality rates within the first 7 days. We used index hospitalizations occurring from January 1, 2020 through June 30, 2020 to identify eligible index hospitalizations and unplanned hospital readmissions. In an analysis of unadjusted readmission and death rates by COVID–19 hospitalization status and days since index discharge, during the first 4 to 7 days after discharge there was a readmission rate of 81.3 percent of dialysis patients hospitalized with COVID–19, as compared to 82.6 percent of dialysis patients hospitalized without COVID–19. During that same 4 to 7 day time period, the unadjusted mortality rate for dialysis patients hospitalized with COVID–19 was 16.9 percent, compared with 10.9 percent of patients hospitalized without COVID–19. Based on this discrepancy, we were concerned about the effects of these observations on the calculations for the SRR clinical measure. The denominator of SRR reflects the expected number of index discharges followed by an unplanned readmission within 4 to 30 days in each facility, which is derived from a model that accounts for patient characteristics, the dialysis facility to which the patient is discharged, and the discharging acute care or critical access hospitals involved. Our analysis indicated potential competing risks of higher mortality and lower readmissions due to patient death or discharge to hospice, both of which would remove them from the denominator for the SRR clinical measure. If readmissions rates are lower because patient mortality is higher due to the impact of COVID–19 on dialysis patients, then readmission rates would be distorted by appearing significantly better compared to historical performance during the immediately preceding program years. Based on the impact of COVID–19 on SRR results, including the deviance in measurement, we concluded that the SRR clinical measure met our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we stated our belief that the resulting performance measurement on the SRR clinical

measure would not be sufficiently reliable or valid for use in the ESRD QIP.

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the SRR clinical measure is an important part of the ESRD QIP Program measure set. However, we were concerned that the PHE for the COVID–19 pandemic affected measure performance on the current SRR clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we stated that we would continue to collect the measure's claims data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

In the proposed rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SRR clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the SRR clinical measure as additional data becomes available. As an alternative approach, we stated that we might also consider eliminating from the calculation of the SRR clinical measure any cases of patients who had a COVID–19 event prior to or at the time of index hospitalization. We stated our belief this approach might help distinguish between ESRD-related readmissions and COVID–19 related readmissions that might otherwise impact SRR clinical measure calculations.

We welcomed public comment on our proposal to suppress the SRR clinical measure for PY 2022. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the SRR clinical measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SRR clinical measure for PY 2022.

d. Suppression of the ICH CAHPS Clinical Measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36353), we proposed to suppress the ICH CAHPS clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. Based on our analysis of CY 2020 ICH CAHPS data, we found a significant decrease in response scores as compared to previous years.

The ICH CAHPS clinical measure is scored based on three composite measures and three global ratings.[120] Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always'' to assess the patient's experience of care at a facility. Facility performance on each composite measure is determined by the percent of patients who choose ''top-box'' responses (that is, most positive or ''Always'') to the ICH CAHPS survey questions in each domain. The ICH CAHPS survey is administered twice yearly, once in the spring and once in the fall.

Because of the ECE we granted in response to the COVID–19 PHE, facilities were not required to submit CY 2020 spring ICH CAHPS data for purposes of the ESRD QIP. On September 2, 2020, we published an interim final rule with comment (IFC) in the **Federal Register** titled, ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820) referred to herein as the ''September 2020 IFC''. In the September 2020 IFC, we noted that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable performance period (85 FR 54829 through 54830). Because the PY 2022 performance period for the ICH CAHPS measure is January 1, 2020 through December 31, 2020, and the ICH CAHPS survey is administered twice a year (once in the spring and once in the fall), in the proposed rule we stated that we only have data available from the fall CY 2020 survey to calculate facility performance on this measure. Therefore, facilities would only be scored on data based on one ICH CAHPS survey administration for CY 2020, rather than two. Even if we were to score facilities based on the one ICH CAHPS survey administered in the fall, our preliminary data indicated that 95 percent of facilities would not be eligible for scoring on ICH CAHPS for CY 2020. By contrast, 58.9 percent of facilities were not eligible for ICH CAHPS during CY 2018. If we were to score the 5 percent of eligible facilities on ICH CAHPS, we stated our belief that there would be a significant deviation in national performance on this measure compared to the national performance based on 41.1 percent of facilities eligible for scoring on ICH CAHPS during 2018 (86 FR 36353). We also stated that this is a significant deviation in national performance on this measure compared to historical performance during the immediately preceding program years. Given this significant deviation in national performance during the PHE, we expressed our belief that the ICH CAHPS clinical measure meets the criteria for Measure Suppression Factor 1.

We also stated our belief that this significant change in performance may unfairly penalize facilities and that suppressing this measure for the PY 2022 program year would address concerns about the potential unintended consequences of penalizing facilities that treat COVID–19 diagnosed patients in the ESRD QIP. As alternative approaches, we considered changing the performance period or scoring facilities on one survey administration, but otherwise meeting the 30 completed surveys requirement. However, we found that neither of these approaches were feasible; extending the performance period would not accurately reflect ICH CAHPS performance during CY 2020, and as discussed above, an estimated 95 percent of facilities would not be eligible for ICH CAHPS scoring on one survey. Therefore, to avoid unfairly penalizing facilities due to their performance on the ICH CAHPS survey for the PY 2022 ESRD QIP, we stated our belief that it is appropriate to suppress the ICH CAHPS measure for CY 2020, which is the performance period for the PY 2022 ESRD QIP program year (83 FR 57010).

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the ICH CAHPS measure is an important part of the ESRD QIP measure set.

[120] Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf.*

However, we were concerned that the COVID–19 PHE affected measure performance on the current ICH CAHPS measure such that we would not be able to score facilities fairly or equitably on it. Additionally, participating facilities would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. In the proposed rule, we stated that we would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe (86 FR 36353). We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

We welcomed public comment on our proposal to suppress the ICH CAHPS measure for the PY 2022 program year. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the ICH CAHPS measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the ICH CAHPS measure for PY 2022.

e. Suppression of the Long-Term Catheter Rate Clinical Measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36353 through 36354), we proposed to suppress the Long-Term Catheter Rate clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. Based on our analysis of Long-Term Catheter Rate clinical measure data during CY 2020, we found a significant increase in long-term catheter use as compared to previous years, which may be the result of hesitancy to seek medical treatment among dialysis patients concerned about being exposed to COVID–19 during the PHE.

In the CY 2018 ESRD PPS final rule, we finalized the inclusion of the Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure in the ESRD QIP measure set beginning with the PY 2021 program (82 FR 50778). The Long-Term Catheter Rate clinical measure is defined as the percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access. The measure is based on vascular access data reported in CROWNWeb (now EQRS) and excludes patient-months where a patient has a catheter in place and has a limited life expectancy.

Our analysis based on the available data indicated that long-term catheter use rates increased significantly during the COVID–19 PHE. Average long-term catheter rates were averaging around 12 percent in CY 2017 and CY 2018. In CY 2019, rates increased to average around 12.25 percent. This increase continued into CY 2020, with rates reaching a peak of 14.7 percent in June 2020 and declining slightly to 14.3 percent in July and August 2020. After remaining around 12 percent for 3 consecutive years, in the proposed rule we stated that we view a sudden 2 percent increase in average long-term catheter rates as a significant deviation compared to historical performance during immediately preceding years (86 FR 36354). We were concerned that the COVID–PHE impacted the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 exposure and increased health risks resulting therefrom, and that these contributed to the significant increase in long-term catheter use rates.

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the Long-Term Catheter Rate clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the PHE for COVID–19 affected measure performance on the current Long-Term Catheter Rate clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, participating facilities would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. In the proposed rule (86 FR 36354), we stated that we would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

We welcomed public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for the PY 2022 program year. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2022.

D. Special Scoring Methodology and Payment Policy for the PY 2022 ESRD QIP

As described in section IV.B.2. of the proposed rule, we have considered the impact of operational systems issues preventing facilities from submitting September through December 2020 patient and clinical data into the EQRS from November 1, 2020 through on or about July 12, 2021. Even when facilities are able to submit the September through December 2020 patient and clinical data by September 1, 2021, we will need time to validate the quality and reliability of the impacted data in order to determine whether all data quality issues have been resolved (86 FR 36354). In addition, as described in section IV.C. we stated our belief that four of the ESRD QIP measures have been impacted by the COVID–19 PHE that could result in distorted measure performance for PY 2022.

It is not our intention to penalize dialysis facilities based on the performance on data that are not reliable, thus, not reflective of the quality of care that the measures in the program are designed to assess. Therefore, we proposed a special rule for PY 2022 scoring for the ESRD QIP under which we would calculate measure rates for all measures, but would not calculate achievement and improvement points for any of them because they have all been impacted by the operational systems issues and, as we stated previously, we believe that four of them have additionally been significantly impacted by COVID–19. Because we would not calculate achievement and improvement scores for any measures, we also proposed under this special rule that we would

not score any of the measures in the four domains or calculate or award Total Performance Scores for any facility. We also proposed to not apply any payment reductions to ESRD facilities for PY 2022.

In order to ensure that a facility is aware of any changes to its measure rates that we have observed, we proposed to provide confidential feedback reports that contain the measure rates we calculated for PY 2022. Performance scores for facilities would be released on Dialysis Facility Compare and footnoted to indicate potential accuracy concerns with the scores. Performance score certificates would be generated with the TPS showing as ''Not Applicable.''

We proposed to codify these policies for PY 2022 at 42 CFR 413.177(a) and 413.178(h).

However, we stated that if the proposed measure suppression policies and proposed special scoring and payment policies in the proposed rule were not finalized, the PY 2022 ESRD QIP payment would be implemented in accordance with our current policy, as well as the payment reduction ranges finalized in the CY 2020 ESRD PPS final rule (84 FR 60725 through 60727).

We invited public comment on this proposed special scoring and payment policy for the PY 2022 ESRD QIP. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for the proposed special scoring methodology and payment policy for PY 2022. Several commenters agreed that quality measure data submitted during the COVID–19 PHE should not be used for performance scoring or payment in the ESRD QIP, and expressed their concerns regarding the impact of the COVID–19 PHE on quality measure data. Several commenters agreed that facilities should not be penalized due to the potential impact of EQRS issues on the reliability and accuracy of the data. One commenter expressed the belief that this proposal would allow staff members to remain focused on COVID–19 safety.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS apply this special scoring methodology and payment policy to PY 2023 and possibly future years, noting the continuing impact of the COVID–19 PHE on facilities and the ESRD patient population. A few commenters expressed the belief that it is appropriate to let the healthcare system stabilize from the effects of the PHE before imposing penalties.

Response: We thank the commenters for this feedback. We acknowledge the continuing impact of the COVID–19 PHE on facilities and the ESRD patient population. We will continue to monitor the impact of the COVID–19 PHE on the ESRD QIP in order to consider, based on the data, whether to propose changes to the scoring methodology for PY 2023.

Final Rule Action: After considering public comments, we are finalizing our special scoring and payment policy for the PY 2022 ESRD QIP as proposed. We are also finalizing our proposal to codify these policies for PY 2022 at 42 CFR 413.177(a) and 413.178(h).

E. Updates to Requirements Beginning With the PY 2024 ESRD QIP

1. PY 2024 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2024 ESRD QIP measure set will include the same 14 measures as the PY 2023 ESRD QIP measure set (85 FR 71465 through 71466). These measures were described in Table 2 in the CY 2022 ESRD PPS proposed rule (86 FR 36355) and are described in Table 2 in this final rule. For the most recent information on each measure's technical specifications for PY 2024, we refer readers to the CMS ESRD Measures Manual for the 2021 Performance Period.[121]

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[121] *https://www.cms.gov/files/document/esrd-measures-manual-v61.pdf*. We note that information for the 2022 Performance Period is also now available at: *https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf*.

TABLE 2: PY 2024 ESRD QIP Measure Set

National Quality Forum (NQF) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on NQF #2979	Standardized Transfusion Ratio (STrR), a reporting measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure Number of patient-months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.

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We discuss our proposal to update the SHR clinical measure in the following section.

a. Update to the Standardized Hospitalization Ratio (SHR) Clinical Measure Beginning With the PY 2024 ESRD QIP

In the CY 2017 ESRD PPS final rule, we adopted the SHR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77906 through 77911). The SHR clinical measure is a National Quality Forum (NQF)-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected

given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.

In the CY 2022 ESRD PPS proposed rule (86 FR 36356), we stated that hospitalizations are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year.[122] Hospitalizations account for approximately 33 percent of total Medicare expenditures for ESRD patients.[123] Studies have shown that improved health care delivery and care coordination may help reduce unplanned acute care including hospitalization.[124] Hospitalization rates vary across dialysis facilities even after adjustment for patient characteristics, suggesting that hospitalizations might be influenced by dialysis facility practices. An adjusted facility-level standardized hospitalization ratio, accounting for differences in patients' characteristics, plays an important role in identifying potential problems, and helps facilities provide cost-effective quality health care to help limit escalating medical costs.

In the CY 2017 ESRD PPS final rule, we finalized our proposal to adopt the SHR clinical measure, which was a modified version of the NQF-endorsed SHR clinical measure (NQF #1463), as part of the ESRD QIP measure set (81 FR 77911). In that final rule, we stated that our modified SHR clinical measure would incorporate 210 prevalent comorbidities into our risk adjustment calculation, as our analyses suggested that incorporating prevalent comorbidities would result in a more robust and reliable measure of hospitalization (81 FR 77906 through 77907). In that final rule, we explained that data used to calculate the SHR clinical measure are derived from an extensive national ESRD patient database (81 FR 77908). We noted that the database is comprehensive for Medicare Parts A and B patients, and that non-Medicare patients are included in all sources except for the Medicare payment records. In that final rule, we also stated that the Standard Information Management System/CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients, and information on hospitalizations and patient comorbidities are obtained from Medicare Inpatient Claims Standard Analysis Files. In the CY 2019 ESRD PPS final rule, we increased the weight of the SHR clinical measure from 8.25 percent to 14 percent of the TPS (83 FR 56992 through 56997).

On November 20, 2020, NQF completed its most recent review of the SHR clinical measure, a measure maintenance review, and renewed the measure's endorsement. As part of this review, the NQF endorsed updating the prevalent comorbidity adjustment, which would group 210 individual ICD–9–CM prevalent comorbidities into 90 condition groups, derived from the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) groups. The updated prevalent comorbidity adjustment would also limit the source of prevalent comorbidities to inpatient claims. The switch to using only Medicare inpatient claims to identify prevalent comorbidities is due to the lack of Medicare outpatient claims data for the growing Medicare Advantage (MA) patient population. By using the original set of Medicare claims datasets (inpatient, outpatient, hospice, skilled nursing, and home health), the NQF stated its concern that MA patient prevalent comorbidities would be systematically biased. These MA patient prevalent comorbidities would only be populated by Medicare inpatient claims, as compared to non-MA patient prevalent comorbidities that would be populated by the aforementioned set of Medicare claim sources. The updated NQF-endorsed SHR clinical measure would also include all time at risk for MA patients, and added a MA indicator for adjustment in the model. The NQF-endorsed specifications also included updates to parameterization of existing adjustment factors and re-evaluation of interactions, and also created three distinct groups of patients to use in the SHR model based on time spent in a skilled nursing facility, noting that nursing home residence is a marker of higher morbidity.

The updated SHR clinical measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[125] When the Measure Applications Partnership Hospital Workgroup convened on January 11, 2021, it reviewed the MUC List, including the SHR clinical measure. The Measure Applications Partnership Hospital Workgroup recognized that hospitalization rates vary across dialysis facilities, even after adjusting for patient characteristics, which suggests that hospitalizations might be influenced by dialysis facility practices. The Measure Applications Partnership Hospital Workgroup also noted that the SHR clinical measure seeks to improve patient outcomes by measuring hospitalization ratios among dialysis facilities, and that the measure seeks to promote communication between the dialysis facilities and other care settings to improve care transitions.[126] In its final report, the Measure Applications Partnership supported this measure for rulemaking.[127]

In the CY 2022 ESRD PPS proposed rule (86 FR 36356), we proposed to update the SHR clinical measure specifications to align with the NQF-endorsed updates. These included updates to the risk adjustment method of the measure, which include a prevalent comorbidity adjustment, the addition of MA patients and a MA indicator in the model, updates to parameterization of existing adjustment factors and re-evaluation of interactions, and an indicator for a patient's time spent in a skilled nursing facility.

In the proposed rule, we expressed our belief that adopting these updates would be consistent with our stated goal of evaluating opportunities to more closely align ESRD QIP measures with NQF measure specifications (84 FR 60724). The SHR clinical measure seeks to improve patient outcomes by measuring hospitalization ratios among dialysis facilities, and we stated our belief that these updates would result in a more reliable and robust SHR clinical measure.

We sought comment on this proposal to update the SHR clinical measure

[122] United States Renal Data System. 2018 United States Renal Data System 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, 2018.

[123] Ibid.

[124] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Advancing American Kidney Health. 2019. Available at: *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

[125] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

[126] Measure Applications Partnership. Measure Applications Partnership Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[127] Measure Applications Partnership. Measure Applications Partnership 2020–2021: Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on April 28, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893.*

specifications for use in the ESRD QIP beginning with PY 2024. The comments we received and our responses are set forth below.

Comment: A few commenters expressed support for the proposed updates to the SHR clinical measure specifications. One commenter noted that such updates are NQF-endorsed and supported by the MAP.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern regarding the proposed updates to the risk adjustment method of the SHR clinical measure and recommended that CMS perform a sensitivity analysis of the risk model fit, comparing the prior risk model's outcomes with the updated risk model's performance to assess the impact of the new approach.

Response: We are finalizing the proposed updates to the SHR clinical measure because they are endorsed by the NQF and would align the specifications of the SHR clinical measure with the NQF-endorsed specifications. Although we are not bound by the NQF's decisions regarding measure specifications, we believe that adopting these updates is consistent with our stated goal of evaluating opportunities to more closely align ESRD QIP measures with NQF measure specifications (84 FR 60724). The updates to the SHR clinical measure were reviewed and endorsed by NQF in 2020. As part of that NQF review, both the current and proposed SHR risk adjustment model results were presented in the Testing Forms and were available for discussion during the NQF review process. In addition, the NQF review included comparisons of both the prior and updated risk adjustment model performance for other aspects of the Scientific Acceptability criteria (reliability and validity). Both the NQF Methodology Panel and Admissions/Readmissions Standing Committee had the opportunity to review the models' performance (that is, the ''risk model fit'') on those and other endorsement criteria prior to NQF's decision to endorse the proposed model changes. Because the NQF review included an analysis of the risk model's performance, we believe that the NQF review effectively constituted a sensitivity review (that is, an analysis of the degree to which the elements of the risk model contribute to the risk of hospitalization) of the proposed specification changes, because it compared all important criteria used by NQF between the prior and proposed versions of SHR.

Comment: A few commenters expressed concern that the proposed update to the comorbidity adjustment may skew the model toward a sicker patient population, noting that the approach would result in inaccurately low hospitalization rates leading to erroneously high scores. One commenter expressed concern that this may be misleading to patients and might disincentivize improvements that might actually lower hospitalizations.

Response: We developed the proposed updated version of the SHR clinical measure to directly correct a progressive bias related to our prior definition of an ''active Medicare patient'' in the context of the rapid increase in Medicare chronic dialysis patients with Medicare Advantage coverage. In the prior version of the SHR clinical measure, ''active'' Medicare status was defined by ''use'' criteria. An individual patient met our use criteria if they either had $900 or more in paid Medicare outpatient dialysis claims or an acute inpatient hospitalization. Either claims-based criterion conveyed active Medicare status for purposes of the measure for the event month and two consecutive following months. Nearly all Medicare fee-for-service patients meet the use criterion of $900 paid claims for dialysis because this amount reflects between 2 to 3 outpatient dialysis treatments at current reimbursement rates. However, the only MA patients meeting these use criteria were those hospitalized in the year. As a result, the time at risk calculated in the old SHR clinical measure underestimated the time at risk for MA patients because not all are hospitalized in a year and virtually no MA patients meet the other use criterion, due to CMS' lack of access to outpatient claims for MA enrollees. The proposed updated version of the SHR clinical measure currently utilizes Medicare's Enrollment Database to identify Medicare Advantage patient status monthly. Combined with our patient-level treatment history file, we are able to calculate true MA patient time at risk at a given dialysis facility, without bias from the ''use'' test.

For the purposes of identifying co-morbidities from Medicare Claims for risk adjustment, we use all inpatient claims in the prior calendar year. We are able to obtain inpatient claims for both Medicare fee-for-service patients as well as MA patients, as hospitals and other inpatient providers furnish inpatient claims for MA patients to their Medicare Administrative Contractors (MACs) for informational purposes. For beneficiaries enrolled in Medicare Advantage, those inpatient claims are often referred to as ''shadow'' claims, as they are not used for direct billing. For Medicare Fee-for Service beneficiaries, we only use paid inpatient claims. Unlike for Medicare fee-for-service beneficiaries, CMS has virtually no access to outpatient claims for Medicare Advantage beneficiaries. We no longer use outpatient claims sources to identify co-morbidities, eliminating potential bias related to the lack of access to outpatient claims for MA patients. Identification of prevalent comorbidities based on only inpatient claims results in fewer comorbidities for each patient compared to use of the universe of Medicare claims. However, use of only inpatient claims results in similar numbers and types of comorbidities for MA patients and other Medicare patients. For instance, in an analysis of a set of comorbidity groups used in a recent SRR calculation, we found that inpatient claims identified 12 comorbid conditions for MA patients on average compared to 12.4 comorbid conditions for other (non-MA) Medicare patients.

In the revised SHR clinical measure, we use all available inpatient claims in the prior calendar year for both Fee-For-Service (FFS) and MA patients. While we agree that limiting co-morbidity ascertainment to inpatient claims results in a less comprehensive set of co-morbidities, our proposed updated risk-adjustment methodology protects against potential bias in determining comorbidity burden due to differences in our access to claims data for FFS and MA patients discussed above. As the SHR clinical measure relies on use of inpatient claims to identify co-morbidities in the prior calendar year, we expect that this lookback period reflects more current conditions that are more likely to be predictive of hospitalization risk. Therefore, we do not believe that outpatient claim derived co-morbidities are as clinically relevant to the risk-adjustment needed for the SHR clinical measure. Moreover, our approach does not require us to exclude MA patients from the measures. We do not want to eliminate a sizable percentage of the current observations from the SHR clinical measure, particularly given the anticipated growth of MA patients with diagnoses of ESRD that will result from changes to the MA program regulations related to the ability of prevalent ESRD patients to choose MA plans beginning in 2021, as finalized in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program final rule

(85 FR 33821 through 33824), which implemented provisions of the 21st Century Cures Act to remove the prohibition on ESRD beneficiaries enrolling in an MA plan.[128] Finally, to account for potential underlying co-morbidity differences between MA and FFS patients that cannot be observed due to potentially incomplete claims-based ascertainment of health status for MA patients, we included all time at risk for Medicare Advantage patients and added a Medicare Advantage indicator for adjustment in the model.

Regarding the possibility that the SHR risk model changes described above would increase model bias, we disagree and believe that the concern that the revised model would bias the SHR toward sicker patients is unfounded. First, we have discussed above the frequency of inpatient claims diagnoses for FFS and MA patients under the new approach. The average number of diagnoses reported from inpatient claims for FFS and MA patients are very similar, strongly suggesting that using only the inpatient claims source is an accurate reflection of the comorbidities for both patient populations. The proposed SHR risk model also includes a Medicare Advantage indicator variable in the model that would guard against bias by minimizing the potential impact of differences in unobserved comorbidities from outpatient claims sources. Considering that the proposed model eliminates a sizeable known bias related to the lack of data about outpatient claims for MA patients, we believe the proposed SHR risk model provides a more accurate representation of dialysis facility performance and, therefore, utility to the dialysis community.

Comment: A few commenters expressed concern regarding the parameterization modifications of existing adjustment factors included in the proposed updates to the SHR clinical measure. Although a few commenters agreed that the updated parameterization of existing adjustment factors and reevaluation of interactions is important, they expressed concern that the p-values, or calculated probability values, of SHR risk models indicate that the model would not be generalizable.

Response: We believe that the proposed risk adjustment model, which includes updates to the parameterization of existing adjustment factors (that is, modifying the functional forms of adjustment factors) and re-evaluation of interactions, is more appropriate because it captures all Medicare patients. Since we are only using the SHR risk models for purposes of the SHR clinical measure, we believe that generalizability is not an issue.

Comment: One commenter requested that CMS indicate how Medicare Advantage patients will be identified under the proposed SHR measure specifications.

Response: Medicare Advantage patient status will be obtained from the Medicare Enrollment Database (EDB). We will confirm the presence of usable ICD diagnosis codes from MA inpatient claims.

Comment: A few commenters recommended that the ESRD QIP should use true risk-standardized rate measures in order to more accurately reflect facility performance, as the ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. One commenter expressed the belief that a more direct, transparent, risk-adjusted rate measure would result in more significant improvement, noting that ESRD patient hospitalization rates have increased between 2016 and 2018 and questioned whether the SHR clinical measure has had a meaningful impact.

Response: We believe that the use of a ratio is appropriate for the SHR clinical measure. The ratio estimate that we proposed is the ratio of the facility adjusted rate to the standard rate. The ratio is also a scientifically valid approach, and ratio measures are well accepted in the published literature. Additionally, the risk-adjustment approach (which is based on application of a specific risk-adjustment model) currently used for the SHR, SRR, and SWR measures leads naturally to a standardized ratio, which compares the rate for this facility with the national rate, having adjusted for the patient mix and is relatively straightforward. We do not believe that rates are more direct and transparent than ratios, and we disagree with the commenter who stated that a risk-adjusted rate measure would lead to significant improvement in performance on the SHR clinical measure. Like ratios, risk-adjusted rates are not the same as actual rates and require a consideration of the patient mix adjustment for interpretation. Furthermore, because the indirect standardized rate is equal to the multiplication of the indirect standardized ratio and a national rate, where the national rate is a constant for all facilities, classifications of facilities based on indirect standardized ratios and rates are equivalent. Finally, we disagree that hospitalization rates have increased between 2016 and 2018. Hospitalization rates have decreased since 2015 as evidenced by the negative coefficients for calendar year from the SHR model. The hospitalization rate for 2016 decreased by 2.7 percent compared to 2015 (p-value <0.0001). Subsequent years had a larger decrease in the hospitalization rate compared to 2015 at 6.8 percent lower for 2017 and about 5.7 percent lower for 2018 (p-value<0.0001 for both) compared to 2015. Although 2018 had a slightly higher rate than 2017, there is an overall downward trend.

Final Rule Action: After considering public comments, we are finalizing our proposal to update the SHR clinical measure specifications for use in the ESRD QIP beginning with PY 2024.

2. Performance Standards for the PY 2024 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Update to the Performance Standards Applicable to the PY 2024 Clinical Measures

Our current policy is to automatically adopt a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year (84 FR 60728). Under this policy, CY 2022 is currently the performance period and CY 2020 is the baseline period for the PY 2024 ESRD QIP. However, under the nationwide ECE that we granted in

[128] The 21st Century Cures Act (Pub. L. 114–255) amended sections 1851, 1852, and 1853 of the Act to expand enrollment options for individuals with ESRD and make associated payment and coverage changes to the MA and original Medicare programs. Specifically, since the beginning of the MA program, individuals with ESRD have not been able to enroll in MA plans subject to limited exceptions. Section 17006(a) of the Cures Act removed this prohibition effective for plan years beginning on or after January 1, 2021.

response to the COVID–19 PHE, first and second quarter data for CY 2020 are excluded from scoring for purposes of the ESRD QIP. In the CY 2022 ESRD PPS proposed rule (86 FR 36357), we stated that we were concerned that it would be difficult to assess levels of achievement and improvement if the performance standards were based on partial year data.[129] Our preliminary analysis indicated that the effect of the excluded data would create higher performance standards for certain measures and lower performance standards for other measures, which may skew achievement and improvement thresholds for facilities and therefore may result in performance standards that do not accurately reflect levels of achievement and improvement.

Our current policy substitutes the performance standard, achievement threshold, and/or benchmark for a measure for a performance year if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than the numerical values for that measure in the previous year of the ESRD QIP (82 FR 50764). We stated in the proposed rule that we adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years (86 FR 36357). However, our general policy provides flexibility to substitute the performance standard, achievement threshold, and benchmark in appropriate cases (82 FR 50764).

Although the lower performance standards would be substituted with those from the prior year, the higher performance standards would be used to set performance standards for certain measures, even though they would be based on partial year data. In the proposed rule (86 FR 36357), we stated that we were concerned that this may create performance standards for certain measures that would be difficult for facilities to attain with a full 12 months of data.

[129] We note that for most ESRD QIP measures, this partial year data would be measure data from July and August 2020.

Therefore, in the CY 2022 ESRD PPS proposed rule (86 FR 36357), we proposed to calculate the performance standards for PY 2024 using CY 2019 data, which are the most recently available full calendar year of data we can use to calculate those standards. Due to the impact of CY 2020 data that are excluded from the ESRD QIP for scoring purposes, we stated our belief that using CY 2019 data for performance standard setting purposes is appropriate. Consistent with our established policy, we would continue to use the prior year's numerical values for performance standard, achievement threshold, and benchmark if the most recent full CY's final numerical values are worse.

We welcomed public comments on this proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposed use of CY 2019 data for calculating performance standards, achievement thresholds, and benchmarks for PY 2024. A few commenters noted that the significant impact of the COVID–19 PHE would make CY 2020 measure data inappropriate for setting PY 2024 performance standards. A few commenters supported the proposal because CY 2019 is the most recently available full calendar year of data.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern with the proposed use of CY 2019 data for calculating performance standards, achievement thresholds, and benchmarks for PY 2024, noting that the ongoing COVID–19 PHE continues to impact measure performance and that using CY 2019 as a pre-pandemic baseline for setting performance standards may unfairly penalize facilities.

Response: We acknowledge the commenter's concern regarding the ongoing impact of the COVID–19 PHE, but disagree that using CY 2019 data for calculating performance standards will unfairly penalize facilities. We note that, due to the nationwide ECE granted in response to the COVID–19 PHE that excluded first and second quarter data from CY 2020, only 6 months of CY 2020 data would be used to calculate performance standards, achievement thresholds, and benchmarks for PY 2024. We believe that there is a greater risk of unfairly penalizing facilities based on performance standards calculated using only 6 months of CY 2020 data, as our preliminary analysis indicated that the effect of the excluded data would create higher performance standards for certain measures and lower performance standards for other measures which may not accurately reflect levels of achievement and improvement.

Comment: One commenter expressed concern that the proposed update only addresses achievement scores, and requested that CMS clarify what year improvement scores will be based on.

Response: We proposed to use CY 2019 data to calculate all performance standards for PY 2024, including achievement and improvement thresholds. This is consistent with the definition of ''performance standards'' codified at 42 CFR 413.178(a)(12), which includes all of the performance levels used to award points to a facility. Therefore, the improvement scores will be calculated using CY 2019 as the baseline year.

Final Rule Action: After considering public comments, we are finalizing our proposal to calculate the performance standards for PY 2024 using CY 2019 data.

b. Finalized Performance Standards for the PY 2024 ESRD QIP

Table 3 displays the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2024 clinical measures, and in the proposed rule we stated that we would use these standards if our proposal to use CY 2019 as the baseline period is finalized (86 FR 36357). As discussed in IV.E.2.a. of this final rule, we are finalizing our proposal to calculate the performance standards for the PY 2024 ESRD QIP using CY 2019 data.

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TABLE 3: Performance Standards for the PY 2024 ESRD QIP Clinical Measures

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Standardized Fistula Rate	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Hypercalcemia	1.54%	0.49%	0.00%*
Standardized Readmission Ratio	1.268*	0.998*	0.629*
NHSN BSI	1.193	0.516	0*
Standardized Hospitalization Ratio	1.230	0.971	0.691
PPPW	8.12%*	16.73%*	33.90%*
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%*	62.22%*	76.57%*
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%
Note: Values marked with an asterisk (*) are also the final performance standards for those measures for PY 2023. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2024 because they are higher standards than the PY 2024 numerical values for those measures.			

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

In addition, we summarize in Table 4 existing requirements for successful reporting on reporting measures in the PY 2024 ESRD QIP. We did not make any proposals to change these standards as a result of the COVID–19 PHE.

TABLE 4: Requirements for Successful Reporting on the PY 2024 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every HD Kt/V session during the week of the monthly Kt/V draw, and the number of sessions of dialysis is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of BUN Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o ARNP, o PA, o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
STrR		At least 10 patient-years at risk during the performance period.

3. Eligibility Requirements for the PY 2024 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 5.

TABLE 5: Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)	10 patient-years at risk	N/A	N/A
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

4. Payment Reduction Scale for the PY 2024 ESRD QIP

Under our current policy, a facility will not receive a payment reduction for a payment year in connection with its performance for the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Our current policy, which is codified at § 413.177 of our regulations, also implements the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

For PY 2024, based on available data, a facility must meet or exceed a mTPS of 57 in order to avoid a payment reduction. We note that the mTPS in this final rule is based on data from CY 2019 because we are finalizing our proposal to calculate the performance standards using CY 2019 data.

We refer readers to Table 3 of this final rule for the finalized values of the 50th percentile of national performance for each clinical measure. We stated in the CY 2022 ESRD PPS proposed rule that under our current policy, a facility that achieves a TPS of 56 or below would receive a payment reduction based on the TPS ranges indicated in Table 6 (86 FR 36360 through 36361). Table 6 of this final rule is a reproduction of Table 6 from the CY 2022 ESRD PPS proposed rule without any changes.

TABLE 6: Estimated Payment Reduction Scale for PY 2024 Based on CY 2019 Data

Total performance score	Reduction (%)
100-57	0%
56-47	0.5%
46-37	1.0%
36-27	1.5%
26-0	2.0%

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In the CY 2022 ESRD PPS proposed rule (86 FR 36361), we stated that if we did not finalize the proposed update to our performance standards policy as described in the proposed rule (86 FR 36357), then we would update the mTPS for PY 2024, as well as the payment reduction ranges for that payment year, in the CY 2022 ESRD PPS final rule using data from CY 2020. However, as discussed in section IV.E.2.a. of this final rule, we are finalizing as proposed the update to our performance standards for PY 2024, and therefore we will use the mTPS and payment reduction ranges for PY 2024 that are described in Table 6.

F. Updates for the PY 2025 ESRD QIP

1. Continuing Measures for the PY 2025 ESRD QIP

Under our previously adopted policy, the PY 2024 ESRD QIP measure set will also be used for PY 2025. We did not propose to adopt any new measures beginning with the PY 2025 ESRD QIP.

2. Performance Period for the PY 2025 ESRD QIP

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2023 as the performance period and CY 2021 as the baseline period for the PY 2025 ESRD QIP.

We did not propose any changes to this policy.

3. Performance Standards for the PY 2025 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively. In section IV.E.2.a. of this final rule, we note that we are finalizing our proposal to use CY 2019 data for purposes of calculating the performance standards for PY 2024 because, due to the anticipated impact of CY 2020 data that is excluded from the ESRD QIP for scoring purposes during CY 2020, we believe that using CY 2019 data for performance standard setting purposes would be appropriate.

a. Performance Standards for Clinical Measures in the PY 2025 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures for the PY 2025 ESRD QIP because we do not have CY 2021 data. We intend to publish these numerical values, using CY 2021 data, in the CY 2023 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2025 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). In the CY 2022 ESRD PPS proposed rule (86 FR 36361), we stated that we will continue use of these performance standards in PY 2025.

4. Scoring the PY 2025 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(e).

We did not propose any changes to this policy for PY 2025.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the MedRec reporting measure and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STrR reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). In the CY 2021 ESRD PPS final rule, we finalized our updated scoring methodology for the Ultrafiltration Rate reporting measure (85 FR 71468 through 71470).

We did not propose any changes to these policies for PY 2025.

5. Weighting the Measure Domains and the TPS for PY 2025

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729). We did not propose any updates to these policies for PY 2025.

G. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

1. Closing the Health Equity Gap in CMS Quality Programs Request for Information

Persistent inequities in health care outcomes exist in the United States (U.S.), including among Medicare patients. In recognition of persistent health disparities and the importance of closing the health equity gap, in the CY 2022 ESRD PPS proposed rule we requested information on expanding several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity, and disability more comprehensive and actionable for dialysis facilities, providers, and patients (86 FR 36362 through 36369). The RFI that was included in the proposed rule is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies. This RFI contained four parts:

- *Background.* This section provided information on existing statements describing our commitment to health equity, and existing initiatives with an emphasis on reducing disparity.
- *Current CMS Disparity Methods.* This section described the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results.* This section described four potential future expansions of the CMS Disparity Methods, including (a) Future potential stratification of quality measure results by dual eligibility; (b) Future potential stratification of quality measure results by race and ethnicity; (c) Improving Demographic Data Collection; and (d) Potential Creation of an *ESRD Facility Equity Score* to Synthesize Results Across Multiple Social Risk Factors.
- *Solicitation of public comment.* This section specified 11 requests for feedback on these topics. We reviewed feedback on these topics and note our intention for an additional RFI or rulemaking on this topic in the future.

a. Background

Significant and persistent inequities in health care outcomes exist in the U.S.[130] Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[131 132 133 134 135 136 137 138] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and operative complications.[139 140 141 142 143 144] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[145 146 147 148 149] Although Black Americans represent 7.5 percent of all older adult Medicare beneficiaries, they represent 28 percent of those with ESRD.[150] Among individuals with ESRD the odds of 30-day hospital readmission are 19 percent higher for Black beneficiaries as compared with white beneficiaries.[151] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and

[130] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[131] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[132] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[133] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[134] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[135] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[136] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[137] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[138] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7386532/.*

[139] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[140] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[141] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[142] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[143] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[144] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[145] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[146] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[147] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[148] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[149] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[150] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.*

[151] Ibid.

stroke.[152] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to white persons.[153] [154] In the ESRD patient population, one study found that the rate of COVID–19 hospitalizations among dialysis patients peaked at 40 times higher than the rate in the general population during the pandemic, with Black, Latino, and Asian persons hospitalized at a higher rate than white persons.[155] As noted by the Centers for Disease Control and Prevention, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.''[156] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[157] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [158] We note that this definition was recently established by the Biden administration, and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Networks and Quality Improvement Organizations (QIN–QIOs); Federal, State, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[159] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[160] The CMS Quality Strategy [161] and Meaningful Measures Framework [162] include elimination of racial and ethnic disparities as a central principle. Our efforts aimed at closing the health equity gap to date have included both providing transparency of health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers on gaps in quality in the following:

- The *CMS Mapping Medicare Disparities Tool* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[163]
- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report,* which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[164]
- The *Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[165]
- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).
- The *CMS Innovation Center's Accountable Health Communities Model* which includes standardized collection of health-related social needs data.
- The *Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders reduce readmissions in diverse populations.[166]
- The *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams in order to enhance care for vulnerable patients with chronic kidney disease (CKD) and are at risk of progression of disease or complications. The guide provides information about disparities in the care of patients with CKD, presents potential actions that

[152] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[153] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[154] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[155] Weinhandl ED, Wetmore, JB, Peng Y, et al. Initial effects of COVID–19 on patients with ESKD. J Am Soc Nephrol. Published online April 8, 2021.doi:10.1681/ASN.2021010009.

[156] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[157] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[158] *https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[159] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[160] Centers for Medicare & Medicaid Services Office of Minority Health. Paving The Way To Equity: A Progress Report. 2015–2021. *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[161] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[162] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[163] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[164] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[165] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[166] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

may improve care, and suggests other available resources that may be used by primary care practice teams in caring for vulnerable patients.[167]

• *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmissions Reduction Program (see 84 FR 42496 through 42500 for a discussion of using stratified data in additional measures).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM)[168] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE)[169] which have examined the influence of social risk factors on several of our quality programs. In this request for public comment, we addressed only the eighth initiative listed above, the CMS Disparity Methods, which we have implemented for measures in the Hospital Readmissions Reduction Program and are considering in other programs, including the ESRD QIP. We discussed the implementation of these methods to date and presented considerations for continuing to improve and expand these methods to provide providers and ultimately consumers with actionable information on disparities in health care quality to support efforts at closing the equity gap.

b. Current CMS Disparity Methods

We first sought public comment on potential confidential and public reporting of ESRD QIP measure data stratified by social risk factors in the CY 2018 ESRD PPS proposed rule (82 FR 31202). We initially focused on stratification by dual eligibility, which is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[170] This report found that in the context of value-based purchasing (VBP) programs, dual eligibility was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

In the FY 2018 IPPS/LTCH PPS final rule, we also solicited feedback on two potential methods for illuminating differences in outcomes rates among patient groups within a provider's patient population that would also allow for a comparison of those differences, or disparities, across providers for the Hospital IQR Program (82 FR 38403 through 38409). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. In the CY 2018 ESRD PPS proposed rule (82 FR 31202 through 31203), we also specifically solicited feedback on which social risk factors provide the most valuable information to stakeholders. In addition, feedback was solicited on the methodology for illuminating differences in outcomes rates among patient groups within a provider's patient population that would also allow for a comparison of those differences, or disparities, across providers. Overall, comments supported the use of dual eligibility as a proxy for social risk, although commenters also suggested investigation of additional social risk factors, and we continue to consider commenter suggestions for which risk factors provide the most valuable information to stakeholders.

c. Future Potential Expansion of the CMS Disparity Methods to the ESRD QIP

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[171] As we previously noted, we have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We sought public comment on the potential stratification of quality measures in the ESRD QIP across two social risk factors: dual eligibility and race/ethnicity.

(1) Stratification of Quality Measure Results—Dual Eligibility

As described in the previous section, landmark reports by NASEM[172] and ASPE,[173] which have examined the influence of social risk factors on several of our quality programs, have shown that in the context of VBP programs, dual eligibility, as an indicator of social risk, is a powerful predictor of poor health outcomes. We are considering stratification of quality measure results in the ESRD QIP and are considering which measures would be most appropriate for stratification and if dual eligibility would be a meaningful social risk factor for stratification.

For the ESRD QIP, we would consider disparity reporting using two disparity methods derived from the Within-Facility and Across-Facility methods. The first method (based on the Within-Hospital disparity method, described previously) would aim to promote quality improvement by calculating differences in outcome rates between dual and non-dual eligible patient groups within a facility while accounting for their clinical risk factors. This method would allow for a comparison of those differences, or disparities, across facilities, so facilities could assess how well they are closing disparity gaps compared to other facilities. The second approach (based on the Across-Hospital method) would be complementary and assesses facilities' outcome rates for subgroups of patients, such as dual eligible patients, across facilities, allowing for a comparison among facilities on their performance caring for their patients with social risk factors.

(2) Stratification of Quality Measure Results—Race and Ethnicity

The Administration's Executive Order on Advancing Racial Equity and Support for Underserved Communities

[167] CMS. Chronic Kidney Disease Disparities: Educational Guide for Primary Care. February 2020. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[168] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[169] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[170] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[171] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[172] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[173] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

Through the Federal Government directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal programs. As summarized earlier in the preamble, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications.[174] We also note that the prevalence of ESRD is higher among racial minorities.[175] For example, in 2016 ESRD prevalence was approximately 9.5 times greater in Native Hawaiians and Pacific Islanders, 3.7 times greater in African Americans, 1.5 times greater in American Indians and Alaska Natives, and 1.3 times greater in Asians.[176] An important part of identifying and addressing inequities in health care is improving data collection to allow us to better measure and report on equity across our programs and policies. We are considering stratification of quality measure results in the ESRD QIP by race and ethnicity, and are identifying which measures would be most appropriate for stratification.

As outlined in the 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, the racial and ethnic categories which may be used for reporting the disparity methods are considered to be social and cultural, not biological or genetic.[177] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[178] Another example, the ''Race & Ethnicity—CDC'' code system in Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS)[179] permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. The Office of the National Coordinator for Health Information Technology (ONC) includes both the CDC and OMB standards in its criterion for certified health IT products.[180] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using *any* of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in PHIN VADS, as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. However, historical inaccuracies in Federal data systems and limited collection classifications have contributed to the limited quality of race and ethnicity information in our administrative data systems.[181] In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive race and ethnic identification.[182] [183] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying white and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander and American Indian/Alaskan Native race.[184] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with public and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection[185] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[186]

ONC included social, psychological, and behavioral standards in the 2015 Edition health information technology certification criteria (2015 Edition), providing interoperability standards LOINC (Logical Observation Identifiers Names and Codes) and SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health

[174] *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[175] United States Renal Data System. 2018 Annual Data Report: ESRD Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Available online at *https://www.usrds.org/2018/view/Default.aspx.*

[176] United States Renal Data System. 2018 Annual Data Report, Vol 2, Figure 1.12. Available online at *https://www.usrds.org/2018/view/Default.aspx.*

[177] Executive Office of the President Office of Management and Budget, Office of Information and Regulatory Affairs. Revisions to the standards for the classification of federal data on race and ethnicity. Vol 62. **Federal Register**. 1997:58782–58790.

[178] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[179] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

[180] ONC criteria for certified health IT products: *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity.*

[181] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[182] Filice CE, Joynt KE. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017;55(12):e170–e176. doi:10.1097/MLR.0000000000000608.

[183] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[184] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[185] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[186] *https://pubmed.ncbi.nlm.nih.gov/18567241/*, *https://pubmed.ncbi.nlm.nih.gov/30506674/*, Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Finance Rev.* 2008;29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019;54(1):13–23. doi:10.1111/1475–6773.13099.

information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) Z-codes, the alphanumeric codes used worldwide to represent diagnoses.[187]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and Census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[188] Indirectly estimated data are most commonly used at the population level (such as the facility or health plan-level), where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[189]

As discussed earlier in the preamble, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach, developed by our contractor, uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, State of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian Pacific Islander (API).[190] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[191]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[192] Validation testing reveals concordances with self-reported race and ethnicity of 0.96–0.99 for API, Black, Hispanic, and White beneficiaries for MBISG version 2.1.[193] [194] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian or Alaskan Native as well as for those who self-identify as multiracial.[195] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration there remains the small risk of unintentionally introducing bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this amount of bias is considerably less than would be expected if stratified reporting was conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for enhancing demographic data collection. We expressed interest in learning more about, and solicited comments about, the potential benefits and challenges associated with measuring facility equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(3) Improving Demographic Data Collection

Stratified facility-level reporting using indirectly estimated race and ethnicity and dual eligibility would represent an important advance in our ability to provide equity reports to facilities. However, self-reported disability status, race, ethnicity, sexual orientation and gender identity data remain the gold standard for classifying an individual according to disability status, race, or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[196] Collection and

[187] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[188] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[189] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[190] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[191] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23.

[192] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[193] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Services Research, 54:13–23.

[194] *https://www.cms.gov/files/document/racial-ethnic-gender-disparities-health-care-medicare-advantage.pdf.*

[195] Haas, A., Elliott, M. et al. (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[196] The Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/*

sharing of a standardized set of social, psychological, and behavioral data by facilities, including disability status and race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[197] This could potentially include expansion to additional social risk factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We are also interested in learning about and solicited comments on current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, and disability status). Further, we are interested in potential challenges facing facility collection of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [198]) and standards for interoperable exchange (such as the U.S. Core Data for Interoperability put forth by ONC for incorporation in certified health IT products as part of the 2015 Edition of health IT certification criteria [199]). Advancing data interoperability through collection of a minimum set of demographic data collection has the potential for improving the robustness of the disparity methods results, potentially permitting reporting using more accurate, self-reported, information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

(4) Potential Creation of an ESRD Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

As we describe previously, we are considering expanding the disparity methods to include two social risk factors (dual eligibility and race/ethnicity). This approach would improve the comprehensiveness of health equity information provided to facilities. Aggregated results from multiple measures and multiple social risk factors, from the CMS Disparity Methods, in the format of a summary score, can improve the usefulness of the equity results. In working with our contractors, we recently developed an equity summary score for Medicare Advantage contract/plans, the Health Equity Summary Score (HESS), with application to stratified reporting using two social risk factors: Dual eligibility and race and as described in Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score.[200]

The HESS calculates standardized and combined performance scores blended across the two social risk factors. The HESS also combines results of the within-plan (similar to the Within-Facility method) and across-plan method (similar to the Across-Facility method) across multiple performance measures.

We are considering building an *ESRD Facility Equity Score,* not yet developed, which would be modeled off the HESS but adapted to the context of risk-adjusted facility outcome measures and potentially other ESRD QIP quality measures. We envision that the *ESRD Facility Equity Score* would synthesize results for a range of measures and using multiple social risk factors, using measures and social risk factors which would be reported to facilities as part of the CMS Disparity Methods. We believe that creation of the *ESRD Facility Equity Score* has the potential to supplement the overall measure data already reporting on the *Care Compare* or successor website, by providing easy to interpret information regarding disparities measured within individual facilities and across facilities nationally. A summary score would decrease burden by minimizing the number of measure results provided and providing an overall indicator of equity.

The *ESRD Facility Equity Score* under consideration would potentially:

- Summarize facility performance across multiple social risk factors (initially dual eligibility and indirectly estimated race and ethnicity, as described above).
- Summarize facility performance across the two disparity methods (that is, the Within-Facility Disparity Method and the Across-Facility Disparity Method) and potentially multiple measures.

Prior to any future public reporting of stratified measure data using indirectly estimated race and ethnicity information, if we determine that an *ESRD Facility Equity Score* can be feasibly and accurately calculated, we would provide results of the *ESRD Facility Equity Score,* in confidential facility specific reports which facilities and their ESRD Networks would be able to download. Any potential future proposal to display the *ESRD Facility Equity Score* on the *Care Compare* or successor website would be made through future RFI or rulemaking.

d. Solicitation of Public Comment

We sought comment on the possibility of stratifying ESRD QIP measures by dual eligibility and race and ethnicity. We solicited public comments on the application of the within-facility or across-facility disparities methods if we were to stratify ESRD QIP measures. We also sought comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification. In addition, we sought comment on the potential design of a facility equity score for calculating results across multiple social risk factors and measures, including race and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and any potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice-and-comment rulemaking. We plan to continue working with ASPE, facilities, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We noted for readers that responses to the RFI will not directly impact payment decisions. We also noted our intention for additional RFI or rulemaking on this topic in the future.

Specifically, we invited public comment on the following:

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.

[197] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

[198] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[199] *https://www.healthit.gov/sites/default/files/2020–08/2015EdCures_Update_CCG_USCDI.pdf.*

[200] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019 Nov 11. doi: 10.1007/s11606–019–05473–x.

Future Potential Stratification of Quality Measure Results

- The possible stratification of facility-specific reports for ESRD QIP measure data by dual-eligibility status, including which measures would be most appropriate for stratification;
- The potential future application of indirect estimation of race and ethnicity information to permit stratification of measure data for reporting ESRD facility-level disparity results;
- Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data is properly identified if/when it is shared with facilities.
- Ways to address the challenges of defining and collecting, accurate and standardized self-identified demographic information, including information on race and ethnicity, disability, and language preference for the purposes of reporting, measure stratification and other data collection efforts relating to quality.
- Recommendations for other types of readily available data elements for measuring disadvantage and discrimination for the purposes of reporting, measure stratification and other data collection efforts relating to quality, in addition, or in combination with race and ethnicity
- Recommendations for types of quality measures or measurement domains to prioritize for stratified reporting by dual eligibility, race and ethnicity, and disability.
- Examples of approaches, methods, research, and/or considerations for use of data-driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in methodology or be encoded in datasets.

We received comments on these topics.

Comments: Many commenters expressed support for stratification by dual eligibility, race, and ethnicity. A few commenters expressed the belief that stratification of quality measures by social risk factors, such as dual eligibility and race and ethnicity, is essential to advancing health equity as such factors have been shown to have a likely impact on health outcomes. A few commenters expressed the belief that stratification will improve transparency, help identify existing disparities and inform efforts to reduce those disparities. A few commenters recommended that CMS take a stepwise approach to stratification. A few commenters stated that stratifying data is important to help identify health equity gaps, but recommended that CMS take action on its findings in order to address the health equity gap and reduce disparities in care. A few commenters recommended that CMS make stratified data publicly available to inform both CMS and stakeholders of the diverse needs of different patient populations, and identify needed policy changes to improve patient access to treatment. A few commenters expressed support for stratification but suggested setting a threshold at the 10th decile of low-income patient distribution to include facilities that serve a disproportionately high percentage of low-income patients. One commenter recommended that adjusting measures for social risk factors, including dual-eligibility or income, may reduce the likelihood of program penalties increasing existing disparities. One commenter supported the proposed stratification of facility-specific reports for ESRD QIP measure data by dual-eligibility status and race and ethnicity; however, this commenter also recommended CMS monitor for unintended consequences believing that stratification risks disparities in patient treatment.

Many commenters expressed support for stratification by dual eligibility. A few commenters supported stratification by dual eligible status, noting that it can be used as a proxy for socio-economic status and is an objective classification that may have less biased data. A few commenters expressed the belief that stratification could help facilities identify and reduce disparities, but noted that differences in Medicaid eligibility between states may impact comparability when stratifying measures by dual eligibility. One commenter expressed concern that dual eligibility may be too blunt a data point to identify the underlying cause of disparity, noting that disparities experienced by ESRD patients stem from a wide range of social risk factors. One commenter noted that understanding differences between dual-eligible and non-dual-eligible patients in baseline chronic kidney disease care could inform ways to allocate resources aimed at slowing the progression of CKD. One commenter noted the correlation between a facility's dual-eligible patient population and a facility's payment reduction based on its ESRD QIP scores, citing studies indicating that facilities serving a higher proportion of dual eligible/low-income patients are more likely to have higher ESRD QIP payment reductions.

Several commenters noted that, although stratification may help identify and address health equity gaps, many disparities begin decades prior to starting dialysis, and encouraged CMS to explore ways to address health disparities earlier in the progression of kidney disease. One commenter expressed concern that stratification may create unintended consequences such as disparities in patient treatment based on social determinants of health. One commenter recommended CMS consider options beyond stratification of ESRD QIP measures by dual eligible status or race and ethnicity to address health equity gaps. One commenter expressed its belief that the segmentation of populations using dual eligibility or race and ethnicity as the proxy for ''social risk,'' for example, is problematic and that the primary goal across all CMS programs should be to prioritize self-reported race, ethnicity, and other social determinants of health data as the sole source of stratifying populations to understand disparities.

Many commenters expressed support for stratification of measures by race and ethnicity, noting that such factors have been identified as likely having an impact on health outcomes. A few commenters expressed support for the use of indirect estimation of race and ethnicity for purposes of calculating facility level performance measures as a preliminary step while more precise methods are developed. One commenter expressed support for the expansion of CMS Disparity Methods to the ESRD QIP and stratifying by race and ethnicity, both within and across facilities. One commenter recommended that disparities methods should be implemented in a way that is minimally burdensome and confidentially reported.

A few commenters requested clarification regarding the application of disparity methods to the ESRD QIP, noting that disparity methods are currently applied to hospital readmissions measures which may be linked to factors outside the facility's ability to influence. A few commenters expressed concern regarding the indirect estimation of race and ethnicity, believing that it was not worth the increased and unknown risk of bias that it could unintentionally create and recommended that indirect data be evaluated to ensure CMS is not introducing bias into the system or underestimating or overestimating the quality of care for a certain population. A few commenters expressed concern that the imputation method is imprecise, particularly for indigenous and multi-racial patients and recommended that self-reported data was more accurate. One commenter

questioned whether either of the two disparities methods would help close the health equity gap, and suggested that CMS consider whether an indirect estimation approach might divert resources away from developing better methods. One commenter recommended a step-wise approach to use the ''Within Facility Disparity Method'' before expanding to apply an ''Across-Facility Disparity Method'' to assess how a facility is addressing equity, as well as to better establish what resources may be required to effectively address equity.

Several commenters expressed support for the stratification of the SRR, STrR, and SHR measures by dual-eligibility status and race/ethnicity, noting that evidence has indicated disparities may factor into measure performance in other healthcare settings, and that such stratification may inform clinical practices and care. Several commenters suggested that the vascular access measures are appropriate for stratification by dual eligibility and race/ethnicity. A few commenters also recommended that these measures be stratified by insurance status at the time of dialysis initiation in order to provide insight into patients' abilities to access pre-dialysis care and vascular access placement. A few commenters stated that the PPPW measure is appropriate for potential stratification by dual eligibility status, race/ethnicity, as well as geographic area. A few commenters recommended that stratification is adopted for measures where it has been shown, or is clearly suspected based on research from other care settings, that disparities are driving differences in the outcomes being reported. A few commenters expressed the belief that most ESRD QIP measures would benefit from stratification. One commenter recommended that CMS encourage all health care providers and organizations to collect and stratify both patient and caregiver data for all measures.

A few commenters recommended that CMS develop best practices to ensure the security of data and its utilization, noting the sensitive nature of the data and the importance of gaining beneficiaries' trust. A few commenters agreed that data elements should be subject to existing privacy and security requirements, and recommended that CMS establish an open and transparent process to work with NQF and other stakeholders to develop data options. One commenter expressed its belief in the unassailable importance of privacy safeguards for all uses of sensitive personal information such as race, ethnicity, and other social risk factors and recommended CMS consider using only self-reported data to alleviate risk of misidentification and to promote robust collection of patient-reported information.

A few commenters expressed the belief that patient self-reporting is the most appropriate way to collect social determinants of health data such as race and ethnicity, agreeing with CMS' assessment that self-reported patient data is the gold standard. A few commenters noted that one challenge may be that the concept of race is subjective and may be imprecise due to differences in cultural understanding. A few commenters recommended that CMS encourage facilities to collect self-reported race and ethnicity data, as well as establish a timeframe for meeting specific data collection goals including data completeness and accuracy requirements. One commenter noted that many health care organizations are already collecting self-reported demographic information and have been for years. One commenter expressed its belief that the primary goal across all CMS programs should be to prioritize self-reported race, ethnicity, and other social determinants of health data as the sole source of stratifying populations to understand disparities. One commenter recommended that, given the importance of self-reported data, CMS work on developing data collection language that is more person-centric in order to encourage trust among those patients whose data are being collected.

Several commenters expressed support for collecting additional information that will likely impact patient outcomes, such as insurance status at dialysis initiation and geographic area of residence. Several commenters recommended the use of Z-codes or other data sources to collect data to report on factors such as housing insecurity, financial insecurity, caregiver support, mental illness, physical illness, age, education level, transportation insecurity, food insecurity, marital status, violence, safety concerns, and child care. One commenter recommended that CMS adopt a definition of health equity that takes into account the needs of various patient populations and structural issues associated with equity, such as race, ethnicity, sex, SOGI, language preference, tribal membership, and disability status.

A few commenters recommended that CMS work with the kidney care community to develop risk adjusters for measures. A few commenters requested that methodologies use data elements that are available to providers and that calculations can be replicated to promote transparency. A few commenters recommended that CMS also consider eliminating bias in kidney function testing, noting for example that the eGFR test is biased based on racial assumptions and can impact transplant eligibility among Black patients. One commenter expressed concern that many approaches based on data-driven technologies are less accessible to vulnerable patient populations and would potentially exacerbate existing inequities. This commenter also noted that smartphone technologies may be more promising as an example of a data-driven technology that does not facilitate exacerbation of health inequities.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

Improving Demographic Data Collection

- Experiences of users of certified health IT regarding local adoption of practices for collection of social, psychological, and behavioral data elements, the perceived value of using these data for improving decision-making and care delivery, and the potential challenges and benefits of collecting more granular, structured demographic information, such as the ''Race & Ethnicity—CDC'' code system.
- The possible collection of a minimum set of social, psychological, and behavioral data elements by ESRD facilities at the time of admission using structured, interoperable electronic data standards, for the purposes of reporting, measure stratification and other data collection efforts relating to quality.

We received comments on these topics.

Comments: Many commenters expressed support for CMS' efforts to address inequities in health outcomes through improving data collection and patient outcome measurement. Several commenters supported the use of minimally burdensome data collection efforts. A few commenters noted that much of the information that CMS would like to collect is reported on Form 2728—ESRD Medical Evidence Report Medicare Entitlement And/Or Patient Registration (OMB control number 0938–0046), and encouraged that CMS to be economical in its expansion of data collection on the Form 2728 so as to not create additional patient concerns. One commenter recommended that a system of data

collection and reporting should not add to the confusion about what the terms race and ethnicity mean, and what labels appropriately fit either of these broad concepts. One commenter recommended that CMS collect data on demographic characteristics in a way that aligns with adoption of FHIR standards, noting that FHIR may be used to appropriately group demographic characteristics in a standardized way. One commenter noted the potential challenge of uploading data from facility EMR systems to CMS for measure calculation purposes. A few commenters expressed concerns with adjusting for social factors when there is a ''small numbers'' problem in ESRD QIP that can impact the accuracy of performance measurement and that will be aggravated with dividing categories into smaller subsets. One commenter expressed its belief that modifications to current data collection related to social, psychological, and behavioral data could be useful to CMS to address equity and quality of care. However, the commenter did not recommend the application of CDC's 900-variable system of identifying race and ethnicity, as provided in the CDC's Race and Ethnicity Code Set Version 1.0, in a highly granular way believing the volume of data that would need to be collected would make the process labor intensive for clinical staff. One commenter recommended that CMS work to improve and standardize the underlying data collection and metrics; this commenter recommended a joint development process that includes the Center for Medicare & Medicaid Innovation (CMMI) and the Office of the National Coordinator for Health Information Technology (ONC) in collaboration with health systems, practices, and patient/community representation.

Other commenters noted the importance of closing the health equity gap through measurement of demographic characteristics. One commenter suggested that agencies leverage the role of social workers in identifying sociodemographic factors and barriers to health equity. Another commenter supported this method, noting that although this may add another step to data collection processes, it would be valuable in addressing health equity gaps. To reduce possible workload burden on organizations that are new to this process, a commenter recommended a gradual approach to data collection. In addition, commenters suggested reducing burden by adopting standardized screening tools to collect this information, such as ICD–10–CM Z-codes, which in practice would allow patients to be referred to resources and initiatives when appropriate. Several commenters encouraged collection of comprehensive social determinants of health and demographic information in addition to race and ethnicity, such as disability, sexual orientation, and primary language. Several commenters provided feedback on the potential use of an indirect estimation algorithm when race and ethnicity are missing or incorrect, and emphasized the sensitivity of demographic information and recommended that CMS use caution when using estimates from the algorithm, including assessing for potential bias, reporting the results of indirect estimation alongside direct self-report at the organizational level for comparison, and establishing a timeline to transition to entirely directly collected data. Commenters also advised that CMS be transparent with beneficiaries and explain why data are being collected and the plans to use these data. A commenter noted that information technology infrastructure should be established in advance to ensure that this information is being used and exchanged appropriately.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

Potential Creation of an ESRD Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

- The possible creation and confidential reporting of an ESRD Facility Equity Score to synthesize results across multiple social risk factors and disparity measures.
- Interventions ESRD facilities could institute to improve a low facility equity score and how improved demographic data could assist with these efforts.

We received comments on these topics.

Comments: Several commenters expressed support for the concept of an ESRD Facility Equity Score, but requested that CMS provide further details. Several commenters recommended that CMS work with stakeholders in the kidney care community to develop an equity score in order to ensure transparency and to make sure providers are able to address identified inequities. One commenter recommended that CMS include education, training, and resources for implementation of an equity score.

A few commenters noted the challenge of developing a scoring methodology that could address risk across different factors. A few commenters questioned whether the score would be meaningful for patients. A few commenters expressed concern for public reporting of a Facility Equity Score, noting that it might be misleading to patients and may not reflect quality of care because facilities are limited in their ability to influence disparities that impact health outcomes. One commenter expressed the belief that a Facility Equity Score is premature, and that CMS should focus on establishing the right set of patient characteristics and contrasting them with meaningful clinical and consumer measures in order to develop a meaningful scoring methodology to propose in future notice and comment rulemaking. One commenter expressed caution that the component measures should reflect actual differences in care provided by ESRD facilities and not factors outside of those facilities' control, believing the inclusion of measures not much under the control of ESRD facilities will penalize those facilities serving a large number of ''vulnerable'' patients and not really speak to issues of equity in the care provided. This commenter recommended that measures are selected carefully to reflect activities and factors that are under facilities' control and then apply all of the standard tools of quality improvement. One commenter expressed its belief that the use of an imputed race/ethnicity methodology risks misattributing people to the wrong categories, and carrying that over into a facility equity score could lead to incorrect or misguided responses. This commenter recommended a careful, inclusive development process to avoid establishing processes and metrics that exacerbate harms and recommended a CMMI initiative to test and shape reporting.

A few commenters expressed support for the production of reports to help facilities, patients and payers understand the disparities in their patient populations. A few commenters noted that many barriers such as anti-kickback rules and other regulations prevent facilities from providing additional services and supports that would help to address health disparities, and recommended that CMS work to find ways to remove these barriers. A few commenters recommended that CMS provide support to facilities in order to help them close gaps in health equity. One

commenter recommended that additional resources be allocated to help assist and support facilities in their health equity goals, such as taking money from ESRD QIP penalties to reward facilities that attain the benchmarks and also allocate funds to help low performing facilities improve. One commenter noted that anything that requires additional staff time and effort without either additional payment or some tangible savings elsewhere, will not be sustainable. This commenter gave examples of care coordination, more time in patient education, more frequent patient home visits, and additional electronic home monitoring, as potential paths to equity improvement that require additional funding.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

We also received comments on the general topic of health equity in the ESRD QIP.

Comments: Many commenters expressed overall support of CMS' goals to advance health equity. There were a few comments regarding the need to further extend and specify the definition of equity provided in the proposed rule. Commenters also noted that equity initiatives should be based on existing disparities and population health goals, be mindful of the needs of the communities served, and work to bridge dialysis facilities with community-based providers. Several commenters recommended that CMS further investigate ways to provide outreach and education aimed at slowing down the progress of chronic kidney disease and address health disparities before dialysis is necessary. Several commenters encouraged CMS to be mindful about whether collection of additional quality measures and standardized patient assessment elements might increase provider burden.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development.

2. COVID–19 Vaccination Measures Request for Information

a. Background

On January 31, 2020, the Secretary declared a PHE for the U.S. in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[201] COVID–19 is a contagious respiratory infection[202] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[203]

As of April 2, 2021, the U.S. reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[204] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[205] From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[206] As of September 16, 2021, the U.S. has reported over 41.5 million cases of COVID–19 and over 666,000 COVID–19 deaths.[207]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[208] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[209] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[210] Although less common, COVID–19 can also spread when individuals are not in close contact if small droplets or particles containing the virus linger in the air after the person who is infected has left the space.[211] Another means of less common transmission is contact with a contaminated surface.[212]

Subsequent to the publication of the proposed rule, the CDC confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[213] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[214] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between healthcare personnel (HCP) and patients, or from patient to patient given the close contact that may occur during the provision of care.[215] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[216]

[201] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[202] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[203] Ibid.

[204] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[205] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[206] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized.*

[207] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[208] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[209] Ibid.

[210] Ibid.

[211] Ibid.

[212] Ibid.

[213] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[214] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[215] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[216] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[217] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[218] Subsequently, FDA issued EUAs for additional COVID–19 vaccines and approved a vaccine.[219]

As part of its national strategy to address COVID–19, the Biden Administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of administering 200 million shots in 100 days.[220] After achieving this goal,[221] the Biden Administration announced a new goal to administer at least one COVID–19 vaccine shot to 70 percent of the U.S. adult population by July 4, 2021.[222] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[223] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[224] Research suggests most states followed this recommendation,[225] and HCP began receiving the vaccine in mid-December of 2020.[226] Although the vaccination strategy for individuals at highest risk for developing severe illness from COVID–19, including ESRD patients, has varied from State to State,[227] ACIP recommendations indicated that ESRD patients would be offered the COVID–19 vaccine based on their high-risk status as part of phase 1c.[228]

As of July 30, 2021 the CDC reported that over 344 million doses of COVID–19 vaccine had been administered, and approximately 164.2 million people had received a complete vaccination course.[229] President Biden indicated on April 6, 2021 that the U.S. has sufficient vaccine supply to make every adult eligible to receive a vaccine beginning April 19, 2021.[230] Furthermore, on March 25, 2021, the Biden Administration announced a new partnership with dialysis facilities to provide COVID–19 vaccinations directly to people receiving dialysis and HCP in dialysis facilities.[231] Finally, as part of the Biden Administration's efforts to vaccinate those who are still unvaccinated through increasing the number of Americans covered by vaccination requirements,[232] on September 9, 2021, the Biden Administration announced that COVID–19 vaccination will be required of all staff within Medicare and Medicaid-certified facilities to protect both patients and HCP against COVID–19.[233]

b. COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

In the CY 2022 ESRD PPS proposed rule (86 FR 36369), we stated our belief that it is important to incentivize and track HCP vaccination in dialysis facilities through quality measurement in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to

[217] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[218] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download.* (as reissued on September 22, 2021)

[219] U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download* (as reissued on August 12, 2021); U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download* (as reissued on June 10, 2021). FDA Approves First COVID–19 Vaccine, Available at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.*

[220] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[221] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/.*

[222] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 4, 2021, at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/04/fact-sheet-president-biden-to-announce-goal-to-administer-at-least-one-vaccine-shot-to-70-of-the-u-s-adult-population-by-july-4th/.*

[223] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[224] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[225] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First? '' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[226] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[227] Kates, J, Michaud, J, Tolbert, J. ''The COVID–19 Vaccine Priority Line Continues to Change as States Make Further Updates.'' Kaiser Family Foundation. January 21, 2021. Accessed on January 29 at *https://www.kff.org/policy-watch/the-covid-19-vaccine-priority-line-continues-to-change-as-states-make-further-updates/.*

[228] Dooling K, Marin M, Wallace M, et al. ''The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID–19 Vaccine—United States, December 2020.'' MMWR Morb Mortal Wkly Rep 2021; 69:1657–1660. ACIP recommended that the COVID–19 vaccine should be offered to persons aged ≥75 years and non-health care frontline essential workers in Phase 1b, and to persons aged 16–64 years with high-risk medical conditions in Phase 1c.

[229] Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. Accessed June 23, 2021 at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[230] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/.*

[231] The White House. FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID–19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities. March 25, 2021. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/.*

[232] The White House. Path Out of the Pandemic: President Biden's COVID–19 Action Plan. Accessed on October 14, 2021. Available at: *https://www.whitehouse.gov/covidplan/#vaccinate.*

[233] CMS. Press Release: Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings. September 9, 2021. Available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.* In order to implement this plan, CMS is working with the CDC to develop an Interim Final Rule with Comment Period that will extend emergency regulations to require vaccination among staff in a wide range of healthcare settings including dialysis facilities. This action will create a consistent standard across the country, while giving patients assurance of the vaccination status of those delivering care.

continue serving their communities throughout the PHE and beyond. We recognize the importance of COVID–19 vaccination, and have finalized proposals to include a COVID–19 HCP vaccination measure in various pay for reporting programs, such as the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (86 FR 45438 through 45446), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (86 FR 42385 through 42396), and the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489). In the proposed rule, we noted that there is not a pay for reporting program under the ESRD PPS, however, we stated our belief that the public reporting of vaccination data on Dialysis Facility Compare is important and would help to inform patients of a facility's COVID–19 vaccination rates of HCP. Currently, there is a measure for HCP [234] and another for patient COVID–19 vaccination [235] rates and such measures are currently reported to CDC's National Healthcare Safety Network via ESRD Networks. The two measures track the proportions of a facility's HCP and patient population, respectively, that have been fully vaccinated against COVID–19. Facilities were able to begin weekly COVID–19 vaccination reporting for HCP in December 2020,[236] and were able to begin weekly COVID–19 vaccination reporting for patients in March 2021.[237] When the proposed rule was published, we noted that 89 percent of ESRD facilities were reporting HCP vaccination rates and almost 95 percent of ESRD facilities were reporting patient vaccination rates on these measures. In the proposed rule (86 FR 36369), we stated that we were evaluating options for publicly reporting the data on official CMS datasets that compare the quality of care provided in Medicare-certified dialysis facilities nationwide. We further stated that we were also exploring the potential future inclusion of a COVID–19 vaccination measure to the ESRD QIP. Therefore, we sought public comment on adding a new measure, COVID–19 Vaccination Coverage Among HCP, to the ESRD QIP measure set in the next rulemaking cycle. The measure would assess the proportion of a facility's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. In the proposed rule (86 FR 36369), we stated our belief that facilities should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[238] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[239] and we stated our belief that HCP COVID–19 vaccination in dialysis facilities could similarly increase uptake among that patient population. We also stated our belief that publishing the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure would address the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

c. COVID–19 Vaccination Coverage for Patients in End-Stage Renal Disease (ESRD) Facilities Measure

In the CY 2022 ESRD PPS proposed rule (86 FR 36370), we stated our belief that it is important to encourage patient vaccination in dialysis facilities in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to continue serving their communities throughout the PHE and beyond. COVID–19 can cause outbreaks in ESRD facilities, and may disproportionately affect ESRD patients due to the nature of the treatment and sharing of common spaces.[240] Many patients treated in ESRD facilities have other underlying chronic conditions, and therefore are highly susceptible to illness and disease.[241] Sufficient vaccination coverage among patients in ESRD facilities may reduce transmission of SARS–CoV–2, thereby protecting them from COVID–19 mortality. Therefore, we sought public comment on adding new measure, COVID–19 Vaccination Coverage Among Patients, to the ESRD QIP measure set in future rulemaking. The measure would assess the proportion of a facility's patient population that has been vaccinated against COVID–19.

In the proposed rule, we stated our belief that facilities should track the level of vaccination among their patients as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. We also expressed our belief that publishing the vaccination rates would be helpful to many ESRD patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

d. Review by the Measures Application Partnership and NQF

The COVID–19 HCP vaccination measure and the COVID–19 patient vaccination measure were included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[242] When the Measure Applications Partnership Hospital Workgroup convened on January 11, 2021, it reviewed measures on the MUC List including the two COVID–19 vaccination measures. The Measure Applications Partnership Hospital Workgroup recognized that the proposed measures represent a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the ESRD QIP measure set by

[234] *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

[235] *https://www.cdc.gov/nhsn/dialysis/pt-covid-vac/index.html.*

[236] *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-guidance-508.pdf.*

[237] *https://www.cdc.gov/nhsn/pdfs/dialysis/covidvax/getting-started-508.pdf.*

[238] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[239] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[240] Verma, A., Patel, A., Tio, M., Waikar, S., ''Caring for Dialysis Patients in a Time of COVID–19''. Kidney Medicine, Volume 2, Issue 6, 2020, Pages 787–792, ISSN 2590–0595. Available at *https://doi.org/10.1016/j.xkme.2020.07.006.*

[241] Ibid.

[242] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[243] The Measure Applications Partnership Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP and ESRD patients, and providing feedback to facilities, will allow facilities to benchmark coverage rates and improve coverage in their facility. The Measure Applications Partnership Hospital Workgroup further noted that reducing rates of COVID–19 in HCP and ESRD patients may reduce transmission among a patient population that is highly susceptible to illness and disease, and also reduce instances of staff shortages due to illness.[244]

In its preliminary recommendations, the Measure Applications Partnership Hospital Workgroup did not support these two measures for rulemaking, subject to potential for mitigation.[245] To mitigate its concerns, the Measure Applications Partnership Hospital Workgroup believed that both measures needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[246] Subsequently, the Measure Applications Partnership Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage Among HCP measure and the COVID–19 Vaccination Coverage for Patients in ESRD Facilities Measure. In the 2020–2021 Measure Applications Partnership Final Recommendations, Measure Applications Partnership offered conditional support for rulemaking contingent on CMS bringing the measures back to Measure Applications Partnership once the specifications are further refined.[247] The Measure Applications Partnership specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [248] The Measure Applications Partnership further noted that the measures would add value to the ESRD QIP measure set by providing visibility into an important intervention to limit COVID–19 infections in HCP and the ESRD patients for whom they provide care.[249] CMS brought both measures back to the Measure Applications Partnership on March 15, 2021 to provide additional information and continue discussing mitigation.

e. Request for Public Comment

In the proposed rule, we sought public comment on potentially adding the two new COVID–19 vaccination measures discussed above, the COVID–19 vaccination measure for HCP and the COVID–19 vaccination measure for patients, to the ESRD QIP measure set.[250]

We were also interested in public comment on data collection, submission, and reporting for the COVID–19 vaccination measure for HCP and the COVID–19 vaccination measure for patients. For example, we stated that we were considering requiring reporting for these measures on an annual basis for the performance period for each calendar year corresponding to the associated payment year, and the reporting period would be January 1 through December 31 annually. Based on the measures currently being developed by the CDC that were submitted to the Measure Applications Partnership, facilities would report the measures through the National Healthcare Safety Network (NHSN) web-based surveillance system. We also sought public comment from stakeholders on other ways to collect data on COVID–19 vaccination rates at dialysis facilities for ESRD QIP purposes and their associated costs and burdens. Given the immediacy of the PHE for COVID–19, as well as the importance of continuing to monitor and make publicly available COVID–19 vaccination rates as the PHE ends, we stated that we anticipate rulemaking on this requirement in the CY 2023 rulemaking cycle.

The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for future adoption of both COVID–19 vaccination measures. Several commenters expressed the belief that COVID–19 vaccination measures are important because they would help to prevent the spread of COVID–19 in a facility and would also help to prevent mortality due to the impact of COVID–19 on an immunocompromised patient population. A few commenters stated that such measures would help encourage COVID–19 vaccination for both staff and patients at ESRD facilities. One commenter noted that the nature of treatment sessions in the dialysis care setting may make other COVID–19 mitigation strategies less effective.

A few commenters expressed support for the possible adoption of both COVID–19 vaccination measures, noting that making such data publicly available would help patients make informed choices. A few commenters expressed support for reporting possible COVID–19 vaccination measures through NHSN as it already does so and therefore would be less burdensome.

Several commenters expressed support for tracking and reporting COVID–19 vaccination rates among HCPs and ESRD patients on Care Compare or Dialysis Facility Compare in order to help patients make informed decisions when choosing a dialysis facility. One commenter expressed support the application of a uniform reporting metric for COVID–19 vaccination among HCPs and patients across all Medicare-covered health settings.

A few commenters expressed support for all efforts to increase vaccination coverage among HCPs for their own safety and for patient safety as well. One commenter expressed its belief that all medically-eligible HCPs should be vaccinated against COVID–19.

A few commenters expressed support for the COVID–19 Vaccination among ESRD patients measure. One commenter expressed the belief that it may be useful for the public to know the percent of patients vaccinated at a facility.

Response: We thank the commenters for their support, and will take commenters' feedback into consideration for future rulemaking.

Comment: Although several commenters expressed support for vaccination efforts and the belief that patients and HCPs should follow CDC vaccination guidelines, these commenters did not support the inclusion of COVID–19 vaccination measures in the ESRD QIP. A few commenters recommended that COVID–19 vaccination measures should not be added to the ESRD QIP, noting the MAP's initial hesitancy to recommend the measures. A few commenters expressed the belief that such measures would not help to address vaccine hesitancy among patients and HCPs, and suggested that Federal agencies

[243] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[244] Ibid.

[245] Ibid.

[246] Ibid.

[247] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.*

[248] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[249] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[250] Specifications for both measures available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.*

coordinate vaccination education and outreach efforts instead. A few commenters expressed concern that including COVID–19 vaccination measures in the ESRD QIP would hold facilities accountable for vaccination rates of patients and HCPs, noting that the individual decision to get vaccinated is beyond the facility's control.

One commenter recommended that such measures incorporate factors that take into account facility vaccination efforts, rather than a numeric threshold. One commenter expressed support for including the COVID–19 vaccination measures as performance measures in the ESRD QIP. One commenter recommended that such measures be included in the ESRD QIP as reporting measures.

Response: We thank the commenters for their feedback, and will take this input into consideration for future rulemaking. We note that the MAP now recommends both COVID–19 vaccination measures for inclusion in the ESRD QIP.[251] We also note that the COVID–19 vaccination measures that we describe in this final rule and are considering for adoption in future rulemaking would be reporting measures. Under these measures, facilities would only be required to report vaccination rates and would not be penalized based on the vaccination rates themselves.

Comment: Several commenters expressed concern that establishing the specifications for such measures would be challenging due to changing COVID–19 vaccination guidelines and differences in regional policies, which may undermine the validity or reliability of a COVID–19 vaccination measure. A few commenters requested that CMS provide more specific details regarding proposed vaccination measure specifications, including defined numerators and denominators, as well as inclusion and exclusion criteria.

A few commenters expressed concern that defining the denominator for the COVID–19 HCP Vaccination measure will be challenging because many ESRD facilities are parts of larger organizations and may share staff who spend some time working in the ESRD unit or facility and time working elsewhere. One commenter requested that the possible COVID–19 Vaccination among HCP measure limit data collection to HCPs employed by the dialysis organizations and only require the reporting of information within the facilities' purview, noting that the CDC is able to obtain non-clinic staff information directly from providers.

Response: We thank the commenters for their feedback, and will take this input into consideration for future rulemaking. We acknowledge that measure specifications may evolve based on changes to COVID–19 vaccination guidelines, and would provide more specific details regarding measure specifications in future rulemaking as part of our proposals to adopt the COVID–19 vaccination measures.

Comment: A few commenters expressed concern that implementing such measures would result in staff quitting in order to avoid vaccination, which would in turn negatively impact patient care.

Response: We acknowledge that staffing shortages are a national issue, especially for the healthcare system. However, we disagree that staffing shortages would impact patient safety more than unvaccinated HCPs. We believe that vaccination is one of the most effective tools right now for protecting an immunocompromised patient population that has particularly high mortality rates due to COVID–19 infection. We also note that the COVID–19 Vaccination among HCP measure that we are considering for future adoption would not require vaccination, but would rather require facilities to report vaccination rates.

Comment: One commenter recommended that patients (such as children 11 and under) who are not yet eligible for vaccination under an EUA or approval should be excluded from any vaccination measure.

Response: The current COVID–19 Vaccination among Patients measure being considered for possible adoption in future rulemaking excludes patients who are ineligible for vaccination.

Comment: A few commenters did not support the future inclusion of a COVID–19 Vaccination among Patients measure. One commenter acknowledged that a COVID–19 patient vaccination measure likely would marginally increase and sustain vaccination rates, but expressed concern that tying a COVID–19 patient vaccination measure to payment may have unintended consequences such as undermining patient autonomy and creating barriers to facility access for unvaccinated patients. One commenter did not support the COVID–19 vaccination measure for patients believing there is no point to collecting data that mostly reflects patient demographics based on vaccination status, not clinical quality. This commenter stated its belief that providers are already motivated to ensure their patients are vaccinated given the high COVID–19 mortality rate among ESRD patients.

Response: The COVID–19 patient vaccination measure that we are considering for adoption in future rulemaking is a reporting measure; facilities would only be required to report vaccination rates and would not be penalized based on actual vaccination rates. We agree that the COVID–19 vaccination measure for patients would collect data that indicates patient vaccination rates at an individual facility. However, we also believe that this measure would motivate providers to ensure their patients are vaccinated against COVID–19 and that this information is also relevant to patient safety since a facility's vaccination rates would be important for patients to know when choosing an individual facility for treatment.

3. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR)

We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As part of this modernization of our quality measurement enterprise, we issued a request for information (RFI). The purpose of this RFI was to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contained four parts:

- *Background.* This part provided information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provided a summary of other recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- *Definition of Digital Quality Measures (dQMs).* This part provided a potential definition for dQMs. Specific requests for input are included in the section.
- *Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.* This part introduced four possible steps that would enable transformation of CMS' quality measurement enterprise to be

[251] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on September 29, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

fully digital by 2025. Specific requests for input are included in the section.

• *Solicitation of Comments.* This part listed all requests for input included in the above sections of this RFI.

a. Background

As required by law, we implemented quality measurement programs and value-based purchasing programs across a broad range of inpatient, outpatient, and post-acute care (PAC) settings, consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. We aim to move fully to digital quality measurement by 2025. We acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness, and therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program that advances the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting quality data via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[252] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health IT as defined in section 4003 of the Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified HL7 Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 as the standard to support Application Programming Interface (API) policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care providers, and health IT developers, HHS can advance-an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of the FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[253] The ONC 21st Century Cures Act final rule also requires health IT developers update their certified health IT to support the U.S. Core Data for Interoperability (USCDI) standard.[254] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[255]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid, and CHIP fee for service programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan [QHP] issuers on the Federally-facilitated Exchanges [FFEs]) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available certain data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule). These certain data include data concerning claims and encounters, with the intent to ensure access to their own health care information through third-party software applications. The rule also established new Conditions of Participation for Medicare and Medicaid participating hospitals, psychiatric hospitals, and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603). In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability programs and the MIPS Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act. Under this policy, eligible clinicians, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT product. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[256]

[252] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[253] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

[254] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[255] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

[256] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://*

This may be further complicated by systems which integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these data to be easily accessible for measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

b. Definition of Digital Quality Measures

In the proposed rule, we sought to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems'' (85 FR 84845). In this RFI, we sought input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also noted that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discuss one potential approach to developing dQM software in section IV.G.3.c. of this final rule. In this section, we sought comment on the potential definition of dQMs in this RFI.

We also sought feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability programs.[257] These fully digital measures continue to be important drivers of interoperability advancement and learning. We are currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. We intend to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

c. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernizing the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and healthcare and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support and care coordination and care decision support, which impacts health care and care quality.

We requested comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

(1) Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated implementation guides) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other

www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.

[257] eCQI Resource Center, *https://ecqi.healthit.gov/.*

dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs set by the ONC 21st Century Cures Act final rule for certified health technology to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825), including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, expressing in standards, exposing via APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to capture all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of electronic data with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning. These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We sought feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We also sought feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcomed comment on approaches for testing data quality and validity.

(2) Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for deploying quality measures to take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR resources maintained by providers, payers, CMS, and others; calculate measure score(s); and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions: (i) Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD); (ii) calculate the measure score according to measure logic; and (iii) generate measure score report(s).
- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation and diffusion of quality measurement and related quality improvement and clinical tools through for example the use of open-source core architecture.

We sought comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We were also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

(3) Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are also considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the Merit-based Incentive Payment System (MIPS) program are potential examples [258] at 42 CFR 414.1440(b)(2)(iv) and (v) and § 414.1440(c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We sought feedback on aggregation of data from multiple sources being used

[258] Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

to inform measurement. We also sought feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

(4) Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets, and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and State agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and State agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[259] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (DoD/VA); the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's Adapting Clinical Guidelines for the Digital Age initiative; the Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, NQF, provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership, which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal and industry, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We sought feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

d. Solicitation of Comments

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. We have summarized the comments to this RFI below but note that we will not be responding to them in this final rule. We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

As noted previously, we sought input on the future development of the following:

• *Definition of Digital Quality Measures:* We sought feedback on the following as described in section IV.G.3.c.(2).:

++ Do you have feedback on the dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcomed more specific comments on the attributes or functions to support such an approach of deploying dQMs.

We received comments on these topics.

Comment: Several commenters expressed support for the proposed definition of dQM. Several commenters recommended additional clarity on the proposed definition of dQM, including more detail on what the measures would be, how they differ from current ESRD QIP measures, and the sources of data for those measures. One commenter recommended that CMS refine its definition of dQMs, focus on currently available valid and reliable digital data sources, and set clear and specific parameters for what they expect of dialysis providers during this transition.

Several commenters expressed support for transitioning toward interoperability through dQMS to interface with FHIR-based resources. One commenter noted that FHIR cannot solve or improve data quality alone without extensive development of FHIR extensions and profiles noting that many ESRD-specific data elements are not part of hospital EHR systems because they are not part of meaningful use requirements; this commenter made recommendations for data elements to be included in future versions of United States Core Data for Interoperability (USCDI). One commenter recommended that CMS evaluate the progress of developers and providers in adopting FHIR standards to ensure that the adoption of FHIR standards is not cost-prohibitive or overly burdensome and that CMS establish a clear timeframe for adoption of FHIR standards, including a trial or voluntary participation period prior to formal adoption. One commenter recommended that CMS ensure that dQMs can be linked with patient-level data such as patient experience of care and patient-reported outcomes. One commenter expressed support for CMS' approach to defining and deploying dQMs on FHIR believing it has the potential to further enhance value-based care that puts patient interests as the focal point. This

[259] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

commenter recommended that implementation of dQMs be gradual, transparent, and based on robust technology. The commenter also noted its belief that the market of software developers would very quickly be able to respond to the CMS request for dQMs. One commenter expressed agreement that data sources should include administrative systems, electronically submitted clinical assessment data, case management systems, electronic health records, instruments such as medical devices or wearable devices, patient portals or applications, health information exchanges or registries, and other sources. One commenter recommended that dQMs be developed using standardized data collection measures that enable end users to interact with quality measures in an interoperable and consistent format and to ensure consistency in the collection and data analysis. This commenter also recommended the use of Smart on FHIR apps using a FHIR Questionnaire to enable powerful data capture, reduce burden, and that would allow for the continuous data driven development of quality measures over time, with the software/hardware layers providing greater stability. One commenter recommended that CMS add a digital measure confirming the presence and accessibility of advance directive information.

Several commenters expressed concerns about shifting to a FHIR-based application programming interface including that the utility of an ESRD-specific FHIR standard outside of quality reporting to CMS is limited, it introduces complicating factors, the burden may outweigh the benefit with CMS' current focus on CROWNWeb and EQRS, it may not achieve the data flow intended by CMS for the dialysis industry, and that shifting to a new system does not make sense at this time. One commenter expressed caution about the adoption of FHIR noting that the current ESRD quality data submission process captures 90 percent of data electronically and recommended piloting the FHIR approach to ensure that FHIR improves quality reporting over and above EQRS. One commenter recommended that CMS consider the burden on facilities related to compliance, noted implementation uncertainties, and recommended CMS allocate resources to help with the transition to new data systems and processes. One commenter expressed concerns with transitioning the ESRD programs to another platform and recommended that interoperability standards should be incorporated into the EQRS. One commenter recommended that CMS not reinvent the wheel but rather continue to work with the kidney care community to address the next generation of quality and data policies.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

• Changes Under Consideration To Advance Digital Quality Measurement: Actions in Four Areas To Transition to Digital Quality Measures by 2025

++ We sought feedback on the following as described in section IV.G.3.c.(1). of this final rule:

—Do you agree with the goal of aligning data needed for quality measurement with that required for interoperability? What are the strengths and limitations of this approach?

—How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

—What are possible approaches for testing data quality and validity?

We received comments on these topics.

Comments: Several commenters expressed support for the goal of aligning data needed with interoperability. One commenter expressed its belief that quality measurement data must be aligned with and based on tools and methods of interoperability within healthcare believing this is core to the achievement of value-based healthcare. This commenter also noted its belief that aligning the incentives for all major stakeholders in healthcare (patients, providers, payers, regulators) is key to enabling a robust healthcare system and that when quality is measured according to the patient through the proxy measures of outcomes and cost of care, having data that are interoperable among these stakeholders is crucial. One commenter expressed support conceptually for the goal of aligning data, but needed more clarity on the specific quality measures CMS is considering for these purposes.

One commenter recommended approaches for standardization including that CMS develop: (1) Standard sets of outcomes measures only utilize validated PROMs as defined by ISOQOL validation guidelines; (2) strictly defined standard sets (standardized outcome definition including allowed response options, validated PROMs and defined data collection time points) ensures consistency in data collection and allow for consistent data quality checks; and (3) variables used in standard sets mapped to SNOMED/LOINC concepts allow for in-depth data validity audits. One commenter recommended that CMS establish guidance to ensure data security and to define roles and responsibilities regarding data validation and data cleaning. This commenter also noted that data validation and cleaning is currently managed by third party intermediaries and is necessary to maintain measure integrity and for reducing provider burden.

One commenter expressed its concerns with standardization including burden on providers and questioned the value of moving from a standardized data format that already serves 90 percent of the dialysis community to an interoperability format that is standardized for data movement between providers beyond the dialysis industry.

A few commenters expressed concerns with the inclusion of patient generated health data and other currently non-standardized data into a data standardized approach. One commenter noted that CMS' definition of patient gathered health data is overly broad. One commenter expressed its belief that such data elements will vary by therapeutic area and be difficult to standardize. One commenter expressed its belief that additional research is needed prior to integration of patient-generated health data into quality measurement believing that while the data can augment the overall picture of health, it can be full of bias, noise, and variability.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

++ We sought feedback on the following as described in section IV.G.3.c.(2). of this final rule:

—What functionalities, described in section IV.G.3.c.(2). of this final rule

or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

—How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

We received comments on these topics.

Comments: One commenter recommended common measure sets that gather data based on standard ontologies (for example, ICD–10, SNOMED–CT) believing that the use of resources that enable the use of shareable, digital data need be part of quality measure tools. The commenter also noted that the use of such measure sets, such as ICHOM Standard Sets, are also essential when on FHIR in a fully interoperable context.

One commenter expressed its belief that broader engagement would lead to incremental gains on quality measure development noting that CMS already provides its contracted measure developers with access to the CROWNWeb and EQRS data for measure development and to the community via USRDS, an NIH sponsored registry, and noted that FHIR API may provide these data in a timelier fashion than providing data files.

One commenter noted that international experience has shown that open cycle work groups, developed under an agile method, leads to the establishment of value based healthcare in a manner that works best for patient outcomes, and in a manner that develops the standards in a way that is independent to the payment rate-setting development process, which can lead to better outcomes for patients and better methods for data collection for providers. This commenter also expressed its belief that making measure collection seamless through the use of standard ontologies and FHIR-based API apps will allow both large scale data collection for use in value-based healthcare initiatives and the local usage of data for improvement of care as well as reducing reporting burden.

One commenter expressed concern that the investments and progress the ESRD community has made to develop the current digital quality framework would be reversed with the adoption of a third new digital quality measurement approach.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

++ We sought feedback on the following as described in section IV.G.3.c.(3). of this final rule:

—Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

—Do you have feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

We received comments on these topics.

Comments: One commenter expressed support for CMS gathering data from multiple sources to inform quality measurement; however, this commenter also expressed caution about the use of FHIR API as the most appropriate digital data collection method. One commenter expressed its belief that CMS is best served to very early define the format in which they need to have the measures reported and that an open publication of the requested data formats and annotation, for example, a common data model, is the key to initiate a health market adjustment. This commenter recommended that CMS set forth policy that requires the collection of data using standardized measure sets, based on easily collectable data (using standard ontologies and PGHD tools), and transported using the FHIR interoperable transport API.

A few commenters expressed their belief that aggregation of data from multiple sources is not an issue for the renal community noting the use of CROWNWeb, EQRS, and HIE.

A few commenters expressed their concerns with the use of data aggregators. One commenter expressed its concerns that moving to an undefined new standard under FHIR will require significant additional investments from industry when such investments already have been made to create the highly efficient HIE and other means of electronic data submission. One commenter expressed its belief that there is no need for data aggregators for the ESRD quality program because of existing data standardization and availability of required data in provider EMRs or CMS claims data noting the successful ability of 90 percent of the industry to submit data electronically in a standard format via batch, and the remaining 10 percent to do the same via manual interface; however, this commenter also noted that if CMS requires data elements that are not able to be collected by dialysis providers then data aggregators may be helpful.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

++ We sought feedback on the following as described in section IV.G.3.c.(4). of this final rule:

—What are initial priority areas for the dQM portfolio (for example, measurement areas, measure requirements, tools)?

—We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

We received comments on these topics.

Comments: One commenter recommended that the priority areas for the dQM portfolio be around health equity and quality measures for which data supports that additional access to care can improve quality outcomes.

A few commenters had recommendations for CMS collaboration related to adopting standards and technology-driven solutions. One commenter recommended opportunities to collaborate with the Social Security Administration, Centers for Disease Control and Prevention, and the United Network for Organ Sharing. One commenter recommended collaboration with an objective, independent and patient centered non-profit organization that collaborates with patients and healthcare professionals. One commenter recommended that CMS work with states and other Federal agencies who might require these same data elements as an API from EQRS then that could create benefit and reduce administrative burden.

Response: We appreciate all of the comments on and interest in this topic.

We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

1. Overview of the ETC Model

As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care.

The ETC Model is a mandatory payment model, as we seek to test the effect of payment incentives on availability and choice of treatment modality among a diverse group of providers and suppliers. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of component ZIP codes [260] located in Maryland. CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD PPS on home dialysis claims, and an upward adjustment to the MCP paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning in January 1, 2021, and ending on December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rate and transplant rate during a Measurement Year (MY), which includes 12 months of performance data. Each MY overlaps with the previous MY, if any, and the subsequent MY, if any, for a period of 6 months. Each MY has a corresponding PPA Period—a 6-month period which begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY. Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to its own home dialysis rate and transplant rate during the Benchmark Year, we make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the ETC Model. These PPAs apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

2. Summary of Proposed Changes to the ETC Model

The proposed rule, 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'' (85 FR 36322 through 36437), referred to herein as the ''CY 2022 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 9, 2021. In the CY 2022 ESRD PPS proposed rule, we proposed a number of policy changes to the ETC Model beginning for the third Measurement Year (MY3) of the Model, which begins January 1, 2022. We proposed changes to the methodology for attributing Pre-emptive LDT Beneficiaries to Managing Clinicians to better reflect the care relationship between beneficiaries who receive pre-emptive LDT transplants and the Managing Clinicians who provide their care. We proposed to include nocturnal in-center dialysis in the numerator of the home dialysis rate calculation for ESRD facilities not owned in whole or in part by a large dialysis organization (LDO) as well as Managing Clinicians, to incentivize additional alternative renal replacement modalities. In addition, we proposed to exclude beneficiaries who are diagnosed with and receiving treatment with chemotherapy or radiation for vital solid organ cancers from the transplant rate to align with common transplant center requirements.

We proposed to modify the PPA achievement benchmarking methodology to increase achievement benchmarks by 10 percent above rates observed in Comparison Geographic Areas every two MYs, beginning for MY3 (2022). We proposed to stratify PPA achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the LIS during the MY, and to introduce the Health Equity Incentive to the PPA improvement scoring methodology, both in an effort to encourage ETC Participants to address disparities in renal replacement modality choice among beneficiaries with lower socioeconomic status. We proposed to modify the PPA improvement benchmarking and scoring methodology to ensure an ETC Participant can receive an improvement score even if its home dialysis rate or transplant rate was zero during the relevant Benchmark Year.

We proposed to add processes and requirements for CMS to share certain model data with ETC Participants. We also proposed an additional programmatic waiver as necessary solely for purposes of allowing Managing Clinicians who are ETC participants to furnish kidney disease patient education services via telehealth under the ETC Model. In addition, we proposed to permit Managing Clinicians who are ETC Participants to reduce or waive beneficiary coinsurance for kidney disease patient education services, subject to certain requirements. In the CY 2022 ESRD PPS proposed rule, we stated our expectation that the proposed changes would continue to

[260] ZIP code™ is a trademark of the United States Postal Service.

promote the larger goals of increased renal replacement modality choice and are based on many of the issues we laid out in the Specialty Care Models final rule as issues for which CMS was considering further rulemaking, including updating benchmarks for ETC Participants and adjusting model parameters based on our implementation experience (86 FR 36376).

3. Impact of the Changes on the ETC Model Evaluation

As we described in the Specialty Care Models final rule, an evaluation of the ETC Model will be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center. We noted that we believe an independent evaluation of the Model is necessary to understand the impacts of the Model on quality of care and Medicare program expenditures (85 FR 61345).

In the CY 2022 ESRD PPS proposed rule (86 FR 36376), we proposed to update the evaluation plan presented in the Specialty Care Models final rule to account for all the policies in that proposed rule, if finalized. However, we noted that changes in the construction of the PPA would have no impact on the evaluation approach to analyzing the final PPA values. This is because the evaluation plan already includes a consideration of the final PPA values, rather than an evaluation of each step in the PPA calculation. However, we stated our expectation that we would conduct subgroup analyses in the evaluation to determine the effect of the proposed Health Equity Incentive, if finalized, in reducing health disparities among beneficiaries with lower socioeconomic status.

As part of the detailed economic analysis included in the CY 2022 ESRD PPS proposed rule and in section VIII.D.4 of this final rule, the transplant waitlist benchmarks were annually inflated by approximately 3-percentage points growth. This was a change from the Specialty Care Models final rule (85 FR 61352), in which the waitlist benchmarks were annually inflated by approximately 2-percentage points growth observed during years 2017 through 2019 to project rates of growth. By increasing the expected effect to a 3-percentage point change, we improve our ability to detect such an effect at the ETC Model's current size. In the Specialty Care Models final rule, we stated that to detect a 2-percentage point increase in the transplant waitlist rate, we would need 30 percent of the 306 HRRs in order to detect an effect of this size with 80 percent power and an alpha of 0.05. Further, we stated that a model of this size would be large enough to detect a one and one-half percentage point change in the home dialysis rate (85 FR 61280). In the CY 2022 ESRD PPS proposed rule (86 FR 36376), we clarified that our unadjusted power calculations show that the model requires 30 percent of the 306 HRRs to detect the one and one-half percentage point change in the home dialysis rate with 80 percent power and an alpha of 0.05. Given the updated expectation that the transplant waitlist rate is likely to increase by 3-percentage points as a result of the ETC Model, the power analysis shows the evaluation would also have sufficient sample size to detect, as statistically significant, a 3-percentage point change in the transplant waitlist rate with 80 percent power and an alpha of 0.05.

We did not receive any comments regarding our proposal to update the evaluation plan presented in the Specialty Care Models final rule to account for all the policies in the CY 2022 ESRD PPS proposed rule, if finalized. We are therefore finalizing our proposal and will modify the model evaluation to analyze the impact of the policies finalized in this final rule.

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Finalized Policies for the ETC Model

The CY 2022 ESRD PPS proposed rule was published in the **Federal Register** on July 9, 2021, with a comment period that ended on August 31, 2021. In that proposed rule, we proposed to make a number of changes to the ETC Model, to begin January 1, 2022, as described previously in section I.B.4 of this rule. We received 64 timely public comments on our proposals, including comments from: ESRD facilities; national renal, nephrologist, and patient organizations; patients; manufacturers; health care systems; and individual clinicians, including nephrologists, nurses, and social workers.

We also received comments related to issues that we did not discuss in the CY 2022 ESRD PPS proposed rule. These include, for example, comments recommending that CMS incorporate staff-assisted home dialysis into the ETC Model, support the training and education of home dialysis nurses, and including transplant providers as ETC Participants. These comments expressed concern over implementing home dialysis programs or the negative payment adjustments included in the Model. While we are generally not addressing those comments in this final rule, we thank the commenters for their input and may consider their recommendations in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ETC Model. These policies take effect January 1, 2022, unless otherwise specified.

Comment: Many commenters supported the goals of the ETC Model. Some of these commenters stated that they appreciate the effort to advance home dialysis during the COVID–19 pandemic since dialyzing at home allows patients to socially distance and avoid going into hospitals or medical centers.

Response: We thank the commenters for the support of the Model's goals.

Comment: One commenter suggested that CMS implement the ETC Model nationwide in order to improve quality of care for all ESRD beneficiaries.

Response: Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving or improving care quality that, if effective, are considered for expansion to the Medicare program. As noted in the Specialty Care Models final rule (85 FR 61280), the randomized selection of 30 percent of HRRs allows CMS sufficient statistical power to assess the effect of the ETC Model. If the test of the ETC Model satisfies the criteria for expansion in section 1115A(c) of the Act, CMS may consider expanding the duration and scope of the ETC Model, including on a nationwide basis.

Comment: One commenter suggested that the ETC Model be an Advanced Alternative Payment Model (APM) allowing ETC Participants to be eligible as qualifying APM participants (QP), similar to what is proposed for the Radiation Oncology (RO) Model.

Regarding the commenter's reference to the RO Model, we finalized our proposal that the RO Model be designed to qualify as an Advanced APM and MIPS APM in the Specialty Care Models final rule (85 FR 61231 through 61238).

Response: As noted in the Specialty Care Models final rule (85 FR 61326), modifying the ETC Model to be an Advanced APM would subject ETC Participants to significant downside risk from the outset, which we believe would put many ETC Participants in a difficult financial position. As further noted in the Specialty Care Models final rule (85 FR 61274), Managing Clinicians may simultaneously participate in the ETC Model and the complementary Kidney Care Choices Model, a voluntary

model we anticipate will meet the criteria to be an Advanced APM beginning in 2022.

Comment: Several commenters urged that patients should have the choice of modality that works best for them, and the ETC Model should support patient choices.

Response: We appreciate the commenters' feedback to support beneficiary choice of treatment modality. The ETC Model, as described in the Specialty Care Models final rule, aims to support beneficiaries choosing alternatives to in-center dialysis. Additionally, ETC Participants are subject to provisions protecting beneficiary freedom of choice set forth at § 512.120 of our regulations, as discussed in the Specialty Care Models final rule (85 FR 61339).

1. Technical Clarifications

For ESRD facilities that are ETC Participants, the ETC Model makes certain upward and downward adjustments to the Adjusted ESRD PPS per Treatment Base Rate for certain dialysis claims via the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The term ''Adjusted ESRD PPS per Treatment Base Rate'' is defined at 42 CFR 512.310 as the per-treatment payment amount as defined in § 413.230 of this chapter, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment, add-on payment amount, outlier payment amount, TDAPA amount, and TPNIES amount. In the CY 2022 ESRD PPS proposed rule (86 FR 36376), we clarified the claims that are subject to adjustment under the ETC Model. Specifically, as § 413.230 is specific to the calculation of payment amounts under the ESRD PPS, we clarify that the HDPA and PPA do not apply to claims from ESRD facilities that are not paid under ESRD PPS and are instead paid through other Medicare payment systems.

We are also updating the name of one of the sources of data used throughout the ETC Model. In the Specialty Care Models final rule, we specified that one source of data for the ETC Model is CROWNWeb, a data management system that CMS uses to collect data from ESRD facilities (85 FR 61317). As we explained in the CY 2022 ESRD PPS proposed rule (86 FR 36376), since publication of the Specialty Care Models final rule, CMS has replaced CROWNWeb with the End Stage Renal Disease Quality Reporting System (EQRS). As such, we will refer to CROWNWeb for data that was generated before the change to EQRS, which CMS began using in 2020, and EQRS for data that was generated after the change to EQRS.

The following is a summary of the comments received on our technical clarifications related to claims subject to adjustment under the ETC Model and the replacement of CROWNWeb data with EQRS data and our responses.

Comment: A few commenters stated that they support the technical clarification that the HDPA and PPA do not apply to claims from ESRD facilities that are not paid under ESRD PPS and are instead paid through other Medicare payment systems.

Response: We appreciate commenters' support for this technical clarification.

Comment: A few commenters stated that they support the technical clarification that the ETC Model will refer to EQRS data in place of CROWNWeb data.

Response: We appreciate commenters' support for this technical clarification.

Comment: A few commenters expressed concerns related to the challenges faced during the transition from CROWNWeb to EQRS, and resulting concerns over data quality.

Response: As discussed elsewhere in this final rule, we are aware of concerns related to the transition from CROWNWeb to EQRS. For the purposes of the ETC Model, we will continue to use the best data available and will work with ETC Participants to address any data issues that arise.

2. Performance Payment Adjustment (PPA) Beneficiary Attribution for Living Kidney Donor Transplants

In the Specialty Care Models final rule (85 FR 61297), we established that beneficiaries are attributed to Managing Clinicians for the purposes of calculating the home dialysis rate and transplant rate. For the home dialysis rate and the transplant waitlist and living donor kidney transplant portions of the transplant rate, as described in 42 CFR 512.360(c)(2)(i), an ESRD Beneficiary is generally attributed to the Managing Clinician with the earliest monthly capitation payment (MCP) claim billed during the month. If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with the same earliest claim service date at the claim line through date for the month, the ESRD Beneficiary is randomly attributed to one of these Managing Clinicians.

However, a beneficiary who receives a pre-emptive living donor transplant (Pre-emptive LDT Beneficiary) is not on dialysis and therefore cannot be attributed to a Managing Clinician using an MCP claim. As a result, under § 512.360(c)(2)(ii), a Pre-emptive LDT Beneficiary is generally attributed to the Managing Clinician with whom the Pre-emptive LDT Beneficiary had the most claims between the start of the MY and the month of the transplant. If no Managing Clinician has had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date during the MY up to and including the month of the transplant, as described in § 512.360(c)(2)(ii)(A). If no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of services for that beneficiary during the MY, and more than one of those Managing Clinicians had the latest claim service date during the MY up to and including the month of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians, as described in § 512.360(c)(2)(ii)(B).

As stated in the CY 2022 ESRD PPS proposed rule (86 FR 36377), upon further review of the beneficiary attribution methodology for living donor kidney transplants, we realized that an unintended consequence of the current attribution methodology is that Pre-emptive LDT Beneficiaries may be attributed to the nephrologist who manages their transplant, not the Managing Clinician who has seen them through the living donor transplant process. As stated in the CY 2022 ESRD PPS proposed rule, to avoid this effect, CMS believes it is necessary to update the attribution methodology for Pre-emptive LDT Beneficiaries. Living donor transplants are relatively rare events that require nephrologist support over time in order to inform beneficiaries of their transplant options and to assist them in finding a living donor. However, the current Pre-emptive LDT Beneficiary attribution methodology is based on visits from the beginning of a MY. As a result, if a Pre-emptive LDT Beneficiary has a transplant early in a MY, the beneficiary may be attributed to a transplant nephrologist who may have had only a single visit with the beneficiary, rather than the Managing Clinician who oversaw the largest share of the care that led to the beneficiary receiving the living donor transplant.

As a result, we proposed to update the attribution methodology for Pre-emptive

LDT Beneficiaries to Managing Clinicians, beginning for MY3, in new provisions at § 512.360(c)(2)(iii). Rather than attributing a Pre-emptive LDT Beneficiary to the Managing Clinician with the plurality of claims from the start of the MY and the month of the transplant, beginning for MY3, we proposed to attribute Pre-emptive LDT Beneficiaries to the Managing Clinician with whom the beneficiary has had the most claims during the 365 days prior to the transplant date. Further, we proposed that if no Managing Clinician has had the most claims for the Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary would be attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant. We proposed that if more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary would be randomly attributed to one of these Managing Clinicians. We proposed that the Pre-emptive LDT Beneficiary would be considered eligible for attribution to a Managing Clinician under this proposed new § 512.360(c)(2)(iii) if the Pre-emptive LDT Beneficiary has at least 1 eligible–month during the 12-month period that includes the month of the transplant and the 11 months prior to the transplant month. We proposed that an eligible month would refer to a month during which the Pre-emptive LDT Beneficiary not does not meet exclusion criteria in § 512.360(b). We proposed changes for Pre-emptive LDT Beneficiary attribution to Managing Clinicians in order to identify and attribute Pre-emptive LDT Beneficiaries to the Managing Clinician who assisted the Beneficiary through the living donor transplant process. We sought comment on these proposed changes for Pre-emptive LDT Beneficiary attribution to Managing Clinicians beginning for MY3 in proposed new § 512.360(c)(2)(iii).

The following is a summary of the comments received on the proposed changes for Pre-emptive LDT Beneficiary attribution to Managing Clinicians beginning for MY3 and our responses.

Comment: Several commenters supported our proposal to update the attribution methodology for Pre-emptive LDT Beneficiaries to Managing Clinicians to identify and attribute Pre-emptive LDT Beneficiaries to the Managing Clinician that assisted the Beneficiary through the living donor transplant process.

Response: We appreciate the support and feedback.

Comment: A few commenters expressed that the proposed changes to the attribution methodology for Pre-emptive LDT Beneficiaries would have a limited impact, due to the small number of Pre-emptive LDT Beneficiaries.

Response: We appreciate the feedback from commenters and recognize the small number of Pre-emptive LDT Beneficiaries. We nonetheless believe it is necessary to update this methodology to ensure that those Pre-emptive LDT Beneficiaries are attributed to the Managing Clinician who oversaw the largest share of the care that led to the beneficiary receiving the living donor transplant to more accurately measure Managing Clinician performance.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.360(c)(2)(iii) to change Pre-emptive LDT Beneficiary attribution to Managing Clinicians beginning for MY3, without modification.

3. PPA Home Dialysis Rate

a. Background on Home Dialysis Rate Calculation

A primary goal of the ETC Model is to support beneficiary modality choice by encouraging ETC Participants to support beneficiaries in selecting alternatives to in-center dialysis. Under 42 CFR 512.365(b), CMS includes in-center self-dialysis treatment beneficiary years in the numerator of the home dialysis rate. Specifically, the home dialysis rate for both Managing Clinicians and ESRD facilities is calculated as the number of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received dialysis at home, plus one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received self-dialysis in center. As described in the Specialty Care Models final rule, we included self-dialysis in the home dialysis rate calculation because we believe in-center self-dialysis may provide a gradual transition from in-center to home dialysis, and provide beneficiaries with the time needed to get comfortable conducting dialysis by themselves, under medical supervision (85 FR 61306).

The denominator for the home dialysis rate is the total dialysis treatment beneficiary years for attributed ESRD beneficiaries during the MY, as described in §§ 512.365(b)(1)(i) and 512.365(b)(2)(i). This includes the months during which attributed beneficiaries received maintenance dialysis at home or in an ESRD facility.

b. Nocturnal Dialysis

Nocturnal in-center dialysis is a form of in-center dialysis conducted overnight for extended hours while the beneficiary is asleep. This dialysis is longer and slower than traditional in-center dialysis, can take more than 5 hours per treatment, and can be performed 3 to 7 days a week. As this type of in-center dialysis is conducted overnight, it allows the beneficiary more time and flexibility to have a continuous job, as well as a social and family life.[261]

Dialysis conducted at a slower rate over a longer period of time is also associated with positive health impacts in comparison to traditional dialysis, including improved blood pressure control, better phosphate control, better management of anemia and bone and mineral metabolism, improved cardiovascular disease, increases in urea reduction ratio, and better beneficiary quality of life measures.[262] [263] [264] [265] [266]

In addition to the clinical benefits, nocturnal in-center dialysis also provides an alternative to traditional in-center dialysis for those beneficiaries for whom home dialysis is not an option

[261] Wilk, Adam S., Lea, Janice P. (2019). How Extended Hemodialysis Treatment Time Can Affect Patient Quality of Life. Clinical Journal of the American Society of Nephrology, 23, 479–485. doi:10.1111/hdi.12782.

[262] Burton, J. and Graham-Brown, M., 2018. Nocturnal hemodialysis. Current Opinion in Nephrology and Hypertension, 27(6), pp.472–477.

[263] Kalim, S., Wald, R., Yan, A.T., Goldstein, M.B., Kiaii, M., Xu, D., . . . Perl, J. (2018). Extended duration nocturnal hemodialysis and changes in plasma metabolite profiles. Clinical Journal of the American Society of Nephrology, 13(3), 436–444. doi:10.2215/cjn.08790817.

[264] Nesrallah, G.E., Lindsay, R.M., Cuerden, M.S., Garg, A.X., Port, F., Austin, P.C., . . . Suri, R.S. (2012). Intensive hemodialysis associates with improved survival compared with CONVENTIONAL HEMODIALYSIS. Journal of the American Society of Nephrology, 23(4), 696–705. doi:10.1681/asn.2011070676.

[265] Wong, B., Collister, D., Muneer, M., Storie, D., Courtney, M., Lloyd, A., . . . Pauly, R.P. (2017). In-center nocturnal hemodialysis versus conventional hemodialysis: A systematic review of the evidence. American Journal of Kidney Diseases, 70(2), 218–234. doi: 10.1053/j.ajkd.2017.01.047.

[276] Wilk, Adam S., Lea, Janice P. (2019). How Extended Hemodialysis Treatment Time Can Affect Patient Quality of Life. Clinical Journal of the American Society of Nephrology, 23, 479–485. doi:10.1111/hdi.12782.

[266] Lacson E, Diaz-Buxo J. In-center nocturnal hemodialysis performed thrice-weekly—a provider's perspective. Semin Dial. 2011 Nov–Dec;24(6):668–73. doi: 10.1111/j.1525–139X.2011.00998.x. Epub 2011 Nov 22. PMID: 22106828.

due to limited financial resources, housing insecurity, lack of social support, or personal preference. For example, a beneficiary experiencing housing insecurity may be unable to dialyze at home due to inability to receive and store home dialysis materials. However, that beneficiary could receive nocturnal in-center dialysis, thereby receiving the clinical benefits of a longer, slower dialysis process and the flexibility associated with not having to receive traditional in-center dialysis during the day.[267] [268]

While nocturnal in-center dialysis offers some of the same clinical and quality of life benefits as home dialysis in comparison to traditional in-center dialysis, use of nocturnal in-center dialysis is rare. Based on analyses described in the CY 2022 ESRD PPS proposed rule and in section VIII.D.4.e of this final rule, less than 1 percent of beneficiaries eligible for attribution to ETC Participants were receiving self-dialysis or nocturnal in-center dialysis in 2019. Potential limitations to nocturnal in-center dialysis utilization include supply factors. At present, few ESRD facilities offer nocturnal dialysis; in 2019, approximately 1 percent of ESRD facilities furnished nocturnal in-center dialysis based on our analysis of claims data. ESRD facilities may face staffing challenges to initiating a nocturnal dialysis program. Potential limitations to nocturnal in-center dialysis also include demand factors: Beneficiaries may be unaware of nocturnal in-center dialysis, or may be averse to sleeping at an ESRD facility or experience difficulty sleeping while receiving dialysis.[269]

c. Inclusion of Nocturnal In-Center Dialysis in Home Dialysis Rate

We proposed to modify the home dialysis rate calculation, for ETC Participants that are either ESRD facilities not owned in whole or in part by an LDO or Managing Clinicians, to include nocturnal in-center dialysis in the numerator beginning for MY3. As described in the CY 2022 ESRD PPS proposed rule and previously in this section of the final rule, we believe this modality allows beneficiaries to continue to receive maintenance dialysis in an ESRD facility under medical supervision, but at a time of day that is more convenient for them, and in a manner that is associated with improved health outcomes. In particular, in the CY 2022 ESRD PPS proposed rule (86 FR 36378), we stated our belief that including nocturnal in-center dialysis in the home dialysis rate may improve access to alternative renal replacement modalities for beneficiaries who are unable to dialyze at home.

In addition to promoting access to the benefits of additional alternative renal replacement modalities for ESRD Beneficiaries who may not be able to dialyze at home, in the CY 2022 ESRD PPS proposed rule we stated our belief that including nocturnal in-center dialysis in the calculation of the home dialysis rate offers an additional pathway to success for ETC Participants with more limited resources. As described in the Specialty Care Models final rule, we received comments that some ESRD facilities, particularly independent ESRD facilities or ESRD facilities owned by small dialysis organizations, may be unable to develop and maintain a home dialysis program (85 FR 61322 through 61324). Operating a home dialysis program requires specialized staff, as well as upfront investment in additional equipment and certification. Establishing a nocturnal in-center dialysis program does not require additional equipment or certification, and may be more feasible for independent ESRD facilities or ESRD facilities owned by small dialysis organizations, and by extension, the Managing Clinicians who serve their patients.

In the CY 2022 ESRD PPS proposed rule (86 FR 36378), we considered including nocturnal in-center dialysis in the numerator of the home dialysis rate for ESRD facilities owned in whole or in part by LDOs as well. However, we noted in the CY 2022 ESRD PPS proposed rule that we do not believe that ESRD facilities owned in whole or in part by LDOs face the same resource constraints in establishing a home dialysis program as independent ESRD facilities or ESRD facilities owned by small dialysis organizations. ESRD facilities owned in whole or in part by LDOs may be more likely to have access to a home dialysis program, either in the ESRD facility itself or within the network of facilities owned by the same parent company in that facility's aggregation group. ESRD facilities owned in whole or in part by LDOs may also have greater access to the upfront capital necessary to establish a home dialysis program if they do not already have, or have access to, a home dialysis program.

At present, there is not a single definition of what qualifies a legal entity that owns ESRD facilities as an LDO. In general, definitions of LDO focus on the number of ESRD facilities owned by the legal entity. Other Innovation Center models have used such definitions: The Comprehensive ESRD Care (CEC) Model defined an LDO as a legal entity owning 200 or more ESRD facilities; the Kidney Care Choices (KCC) Model defines an LDO as a legal entity owning 35 or more ESRD facilities. Outside of Innovation Center models, definitions used by academic researchers vary significantly. For example, in 2015, the United States Renal Data System (USRDS), a national data registry funded by the National Institutes of Health (NIH), defined an LDO as a dialysis organization one that owns and operates 200 or more ESRD facilities.[270] Other academic research has employed thresholds as low as owning 20 or more ESRD facilities and as high as owning 1,000 or more ESRD facilities to consider a legal entity an LDO.[271] [272] Other definitions do not focus on the number of ESRD facilities owned, but on the relative size of dialysis organizations in the market, or rather, the individual dialysis organizations themselves. For example, in its March 2021 report to Congress, the Medicare Payment Advisory Commission (MedPAC) refers to the two largest dialysis organizations in the country as LDOs based on their relative share of ESRD facilities and Medicare treatments.[273]

Based on our review of definitions commonly used, for the purposes of the ETC Model we proposed to define the term ''ETC Large Dialysis Organization,'' abbreviated ''ETC LDO,'' as a legal entity that owns, in whole or in part, 500 or more ESRD facilities (86 FR 36379). Based on the current

[267] Bugeja A, Dacouris N, Thomas A, Marticorena R, McFarlane P, Donnelly S, Goldstein M. In-center nocturnal hemodialysis: Another option in the management of chronic kidney disease. Clin J Am Soc Nephrol. 2009 Apr;4(4):778–83. doi: 10.2215/CJN.05221008. Epub 2009 Apr 1. PMID: 19339410; PMCID: PMC2666425.

[268] Lacson E, Diaz-Buxo J. In-center nocturnal hemodialysis performed thrice-weekly—a provider's perspective. Semin Dial. 2011 Nov–Dec;24(6):668–73. doi: 10.1111/j.1525–139X.2011.00998.x. Epub 2011 Nov 22. PMID: 22106828.

[269] Ibid.

[270] United States Renal Data System. 2015. ''2015 Researcher's Guide to the USRDS Database.'' *https://usrds.org/media/2219/2015_usrds_researchers_guide_15.pdf.*

[271] Mehrotra R, Khawar O, Duong U, Fried L, Norris K, Nissenson A, Kalantar-Zadeh K. Ownership patterns of dialysis units and peritoneal dialysis in the United States: Utilization and outcomes. Am J Kidney Dis. 2009 Aug;54(2):289–98. doi: 10.1053/j.ajkd.2009.01.262. Epub 2009 Apr 8. PMID: 19359081.

[272] Gander JC, Zhang X, Ross K, et al. Association Between Dialysis Facility Ownership and Access to Kidney Transplantation. *JAMA*. 2019;322(10):957–973. doi:10.1001/jama.2019.12803.

[273] Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC. *http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.*

distribution of numbers of ESRD facilities owned by dialysis organizations operating in the market, we stated our belief that this threshold is appropriate, as it differentiates the largest dialysis organizations, which at present own over 2,500 ESRD facilities, from smaller dialysis organizations, the next largest of which owns approximately 350 ESRD facilities. We further stated our belief that the difference in size represents a meaningful difference in access to resources necessary to establish a home dialysis program, as well as the likelihood that an ESRD facility's aggregation group would have at least one ESRD facility with a home dialysis program in the aggregation group. We solicited comment on our proposal to include nocturnal in-center dialysis beneficiary years in the numerator of the home dialysis rate calculation only for ESRD facilities not owned in whole or in part by an ETC LDO, as well as our proposal to define an ETC LDO as a legal entity owning 500 or more ESRD facilities.

While nocturnal in-center dialysis can potentially result in better patient health outcomes and savings to Medicare compared to traditional in-center dialysis, we acknowledged in the CY 2022 ESRD PPS proposed rule that its inclusion in the home dialysis rate may reduce the incentive for ESRD facilities not owned in whole or in part by an LDO to invest in a home dialysis infrastructure. We therefore proposed to include nocturnal in-center dialysis as one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received nocturnal in-center dialysis in the numerator of the home dialysis rate calculation for ESRD facilities not owned in whole or in part by an ETC LDO as well as Managing Clinicians. We further stated our belief that this policy would effectively balance the benefits of nocturnal in-center dialysis and its ability to help beneficiaries transition to home dialysis with the recognition that in-center nocturnal dialysis is not home dialysis and does not have all of the same benefits. As described in the Specialty Care Models final rule, we included one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received self-dialysis in center in the home dialysis rate calculation for a similar reason (85 FR 61306).

As such, we proposed to amend § 512.365(b) such that, beginning for MY3, the numerator for the home dialysis rate for ESRD facilities not owned in whole or in part by an ETC LDO and Managing Clinicians would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home, plus one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via self-dialysis, plus one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via in-center nocturnal dialysis. We further proposed to add paragraph (C) to both §§ 512.365(b)(1)(ii) and 512.365(b)(2)(ii) to specify that nocturnal in-center dialysis beneficiary years included in the numerator of the home dialysis rate calculation would be composed of those months during which attributed ESRD Beneficiaries received nocturnal in-center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary months. The months in which an attributed ESRD Beneficiary received nocturnal in-center dialysis would be identified by claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with the modifier UJ, which specifies that a claim with Type of Bill 072X is for nocturnal in-center dialysis. We sought comment on these proposed changes to § 512.365(b).

The following is a summary of the comments received on our proposal to include nocturnal in-center dialysis in the home dialysis rate beginning for MY3 and our responses, and on the home dialysis rate in general.

Comment: Several commenters expressed support for the ETC Model for creating incentives to increase patient choice in the modality of their dialysis care. A few commenters also expressed support for the Model's potential to close gaps in health equity by making home dialysis more available to previously underserved populations.

Response: We appreciate the feedback and support from commenters.

Comment: A commenter expressed concern that the PPA may not account for barriers to home dialysis such as patient socioeconomic status, energy and infrastructure needs, and caregiver status, and may inadvertently penalize the Managing Clinician if home dialysis is not a suitable option for the beneficiary.

Response: As we noted in the Specialty Care Models final rule (85 FR 61267), we recognize that there are a variety of barriers that prevent ESRD Beneficiaries from choosing home dialysis at present. ESRD facilities and Managing Clinicians are the clinical experts in dialysis provision in general, and in the clinical and non-clinical needs of individual ESRD Beneficiaries specifically. We therefore continue to believe that ESRD facilities and Managing Clinicians are uniquely positioned to assist ESRD Beneficiaries in overcoming these barriers, given their close care relationship to and frequent interaction with ESRD Beneficiaries. Therefore, we have designed the ETC Model to test whether outcomes-based payment adjustments for ESRD facilities and Managing Clinicians can maintain or improve quality and reduce costs by increasing rates of home dialysis, transplant waitlisting, and living donor transplants. The payment adjustments in the ETC Model test one approach to addressing existing disincentives to home dialysis and transplant in the current Medicare FFS payment system.

There are several features of how we assess a Managing Clinician's performance on the home dialysis rate to calculate the Managing Clinician's PPA that address the concern about barriers that prevent individual ESRD Beneficiaries from choosing home dialysis. First, we exclude certain ESRD Beneficiaries from attribution who may not be suitable candidates for home dialysis or transplantation, detailed in § 512.360(b). Second, in this final rule, we are finalizing our proposals to modify the Model's benchmark methodology to recognize the additional resources required to increase the home dialysis rate and transplant rate among beneficiaries who are dual-eligible or LIS recipients. Specifically, as described in section V.B.5.c.(2) of this final rule, we are finalizing our proposal to stratify achievement benchmarks based on dual eligible and LIS recipient status in recognition that socioeconomic factors impact a beneficiary's likelihood of dialyzing at home. Additionally, as described in section V.B.6.c.(2) of this final rule, we are finalizing our proposal to add a Health Equity Incentive to the improvement scoring methodology for ETC Participants who demonstrate sufficiently significant improvement on the home dialysis rate or transplant rate among their attributed beneficiaries who are dual eligible or receive the LIS between the Benchmark Year and the MY. Lastly, as described in section V.B.3.c of this final rule, we are finalizing our proposal to include partial credit for nocturnal in-center dialysis in the home dialysis rate, which may be a more accessible alternative to traditional in-center dialysis for ESRD Beneficiaries facing the barriers identified by the commenter.

Comment: Several commenters expressed their support for nocturnal dialysis as an alternative to traditional in-center dialysis. A few commenters noted that nocturnal in-center dialysis is a valuable treatment option for beneficiaries for whom limited financial resources, housing insecurity, or lack of social support make electing home dialysis difficult, and would thereby promote health equity. A commenter stated that evidence exists to support nocturnal dialysis as an alternative to traditional in-center dialysis because it is associated with improved clinical markers, better sleep and fewer apnea events, and improved nutritional status, and because nocturnal dialysis creates greater opportunity for beneficiaries to hold gainful employment compared to traditional in-center dialysis.

Response: We appreciate the feedback and support from the commenters.

Comment: Multiple commenters expressed agreement with barriers to the provision of nocturnal dialysis identified in the CY 2022 ESRD PPS proposed rule, including supply factors and lack of patient awareness. Commenters also identified system-level factors that may impact an ESRD facility's ability to offer nocturnal dialysis, including labor and operational costs associated with keeping a facility open overnight and the need for additional equipment such as additional water systems to support nocturnal dialysis machines and beds or recliners to facilitate beneficiary sleep. One commenter also noted that beneficiaries would still be required to come into the ESRD facility during traditional hours to receive additional related services, such as nutrition counseling, which cannot be done while the beneficiary is asleep.

Response: We recognize that there are a variety of barriers that prevent ESRD Beneficiaries from choosing nocturnal in-center dialysis at present. As noted previously in this section of this final rule, nocturnal in-center dialysis also provides an alternative to traditional in-center dialysis for those beneficiaries for whom home dialysis is not an option due to limited financial resources, housing insecurity, lack of social support, or personal preference. We believe encouraging the provision of nocturnal in-center dialysis helps to promote beneficiary choice of treatment modalities while mitigating some of the barriers beneficiaries face when considering home dialysis.

Comment: Several commenters expressed their support for including nocturnal in-center dialysis beneficiary years in the numerator of the home dialysis rate calculation. These commenters agreed with CMS's position that incentivizing nocturnal in-center dialysis will create more patient choice and improve health outcomes, and may address certain socioeconomic factors that inhibit beneficiaries from selecting home dialysis.

Response: We agree with commenters that including nocturnal in-center dialysis in the home dialysis rate may improve access for beneficiaries who, due to their home condition, cannot dialyze at home. We believe that supporting patient choice in modality selection is vital, and we believe the ETC Model will support providers and suppliers in their ability to assist beneficiaries choosing renal replacement modalities other than traditional in-center dialysis.

Comment: A few commenters noted that including nocturnal in-center dialysis in the numerator of the home dialysis rate calculation may not provide sufficient incentive for an ESRD facility to launch or expand a nocturnal in-center dialysis program due to increased labor and operational costs. A commenter recommended that to address these challenges, CMS should consider including beneficiaries that are referred to a nocturnal in-center dialysis program in the home dialysis rate numerator.

Response: We recognize that there are a variety of barriers that prevent ESRD facilities from offering nocturnal in-center dialysis. However, we believe including nocturnal in-center dialysis in the home dialysis rate calculation will help promote beneficiary choice of treatment modalities while mitigating some of the barriers beneficiaries face when considering home dialysis. We are not considering including referrals to nocturnal in-center dialysis in the home dialysis rate calculation at this time. We believe the administrative burden associated with tracking referrals may be too great to implement this policy in the ETC Model; however, we may take this recommendation into consideration in the future.

Comment: A few commenters expressed concern that including nocturnal in-center dialysis in the PPA rate may slow adoption of home dialysis, as nocturnal in-center dialysis allows ESRD facilities to use existing the existing in-center dialysis infrastructure rather than modifying or creating new infrastructure and processes to implement a home dialysis program.

Response: A focus of the ETC Model remains promoting beneficiary choice of alternative treatment modalities to traditional in-center dialysis and improving beneficiary adoption of home dialysis. We believe including nocturnal in-center dialysis in the numerator of the home dialysis rate will effectively balance the benefits of nocturnal in-center dialysis and its ability to transition ESRD Beneficiaries to home dialysis, with the recognition that nocturnal in-center dialysis is not home dialysis and does not have all of the same benefits. Specifically, each beneficiary month for which an attributed beneficiary receives nocturnal in-center dialysis will contribute only one-half month to the numerator.

Comment: A commenter urged CMS to further define nocturnal in-center dialysis. The commenter stated that a Medicare manual indicates that nocturnal in-center dialysis should be for periods greater than five hours and performed while the patient is sleeping. The commenter further noted that this definition may allow for in-center dialysis conducted outside of traditional business hours to be considered nocturnal dialysis. The commenter recommended that CMS define nocturnal in-center dialysis as ''in-center hemodialysis treatments dialyzing for at least five hours with a treatment time beginning on one day and terminating after 1 a.m. on the following day'' to avoid confusion and consistency in billing.

Response: As the commenter points out, nocturnal in-center dialysis is already defined by Medicare. Specifically, effective January 1, 2017, nocturnal hemodialysis is identified under the ESRD PPS by the modifier UJ, which identifies services provided at night. The UJ modifier is for ESRD facilities to indicate that the treatment furnished is for nocturnal hemodialysis. That is, longer and slower hemodialysis that can be performed at home or in-facility for greater than 5 hours per treatment, 3 to 7 days a week. Consistent with this definition, as described elsewhere in this final rule, we are finalizing our proposal to identify months in which an attributed ESRD Beneficiary received nocturnal in-center dialysis by claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with the modifier UJ, which specifies that a claim with Type of Bill 072X is for nocturnal in-center dialysis. As such, we do not believe it is necessary to further define nocturnal in-center dialysis in this final rule.

Comment: A few commenters agreed with the proposal to include nocturnal in-center dialysis in the home dialysis rate calculation for Managing Clinicians and for ESRD facilities not owned in whole or in part by an ETC LDO.

Response: We appreciate the commenters' support and feedback.

Comment: Multiple commenters expressed opposition to the proposal to not include nocturnal in-center dialysis in the home dialysis rate for ESRD facilities owned in whole or in part by an ETC LDO. Commenters stated that this policy undermines the incentive to increase access to nocturnal in-center dialysis, as ESRD facilities owned in whole or in part by an ETC LDO provide approximately 75 percent of dialysis care nationally. A few commenters stated that excluding ESRD facilities owned in whole or in part by an ETC LDO from the proposal to include nocturnal in-center dialysis beneficiary years in the numerator of the home dialysis rate calculation may severely limit beneficiary access to the modality, especially beneficiaries in rural and high-poverty areas, which are majority serviced by ESRD facilities owned in whole or in part by an ETC LDO, as these LDOs may not expand their nocturnal in-center dialysis capabilities without the proper incentive. Commenters noted that Managing Clinicians often partner with LDOs and should not be incentivized to refer patients to ESRD facilities not owned in whole or in part by an ETC LDO. Several commenters expressed concern that the proposed policy would arbitrarily apply different standards to ESRD facilities in the Model based on ownership and would set a precedent for future Medicare programs, and may exceed the scope of the Innovation Center's authority.

Response: We agree with commenters that excluding ESRD facilities owned in whole or in part by an ETC LDO from the proposal to include nocturnal in-center dialysis in the home dialysis rate calculation would exclude the majority of beneficiaries from the potential benefits of the policy, as ESRD facilities owned in whole or in part by an ETC LDO provide the majority of dialysis care. We continue to recognize the differences in resource availability to invest in home dialysis programs between ESRD facilities owned in whole or in part by LDOs, and those ESRD facilities that are either independent or owned by small dialysis organizations. However, after considering the comments received, we now believe that it is more important to incentivize access to nocturnal in-center dialysis for all ESRD Beneficiaries, regardless of the ownership of the ESRD facility at which they dialyze. As such, we will not be finalizing the proposal to exclude ESRD facilities owned in whole or in part by an ETC LDO from the modification to include nocturnal in-center dialysis in the home dialysis rate.

Comment: We received multiple comments from multiple smaller dialysis organizations, commonly referred to as non-large dialysis organizations (non-LDO), agreeing with the definition of an ETC LDO as a legal entity that owns, in whole or in part, 500 or more ESRD facilities. These commenters pointed out the resource differential faced by smaller companies from larger companies. Another commenter urged more changes to the ETC Model to relieve potential financial burden for non-LDOs such as including referrals made to nocturnal in-center dialysis programs in the numerator of the home dialysis rate.

Response: As described previously in this section of the final rule, we are not finalizing our proposal include nocturnal in-center dialysis in the numerator only for those ESRD facilities not owned in whole or in part by an ETC LDO. Therefore, we will not be finalizing a definition of an ETC LDO in this final rule. However, we also will not be updating model parameters to include referrals made to nocturnal in-center dialysis programs in the numerator of the home dialysis rate, as suggested by the commenter. As stated previously in this final rule, we believe the administrative burden associated with tracking such referrals may be too great to implement in the ETC Model; however, we may take this recommendation into consideration in the future.

Comment: We received comments from an LDO pointing out that the proposed definition of ETC LDO as a legal entity owning 500 or more ESRD facilities could be viewed as arbitrary, pointing out different definitions used across CMS and in other areas, which range from 20 facilities to 1,000 facilities.

Response: As we noted in the CY 2022 ESRD PPS proposed rule (85 FR 36378), at present there is not a single definition of what qualifies as a legal entity that owns ESRD facilities as an LDO. CMS chose the proposed definition after reviewing definitions commonly used to align with the current distribution of numbers of ESRD facilities owned by dialysis organizations operating in the market. Specifically, our proposed definition differentiated the largest dialysis organizations, which at present each own over 2,500 ESRD facilities, from smaller dialysis organizations, the next largest of which owns under 400 ESRD facilities. This definition is also currently used by the Kidney Care Choices Model, which changed its definition of an LDO after the publication of the CY 2022 ESRD PPS proposed rule, such that the Kidney Care Choices Model now defines an LDO as a legal entity that owns, in whole or in part, 500 or more ESRD facilities. However, as noted above, we will not be finalizing a definition of an ETC LDO in this final rule.

Comment: A few commenters suggested giving ETC Participants who refer patients to home dialysis programs credit in the home dialysis rate, regardless if the home dialysis program is located in the same HRR.

Response: We are not considering this change at this time. As noted previously in this final rule, we believe the administrative burden associated with tracking such referrals may be too great to implement in the ETC Model; however, we may take this recommendation into consideration in the future.

Final Rule Action: After considering public comments, we are finalizing our proposal to amend § 512.365(b) with modification. We are modifying our proposal such that the numerator of the home dialysis rate calculation for all ESRD facilities and for Managing Clinicians includes one half of the total number of nocturnal in-center dialysis beneficiary years for attributed ESRD Beneficiaries. Therefore, we are modifying § 512.365(b)(1)(ii) to remove references to a separate home dialysis rate calculation for ESRD facilities owned in whole or in part by an ETC LDO. Similarly, we are not finalizing the proposed ETC LDO definition at this time.

4. PPA Transplant Rate

a. Status of Organ Availability

The ETC Model is designed to encourage greater rates of transplantation. In the proposed rule published on July 18, 2019 in the **Federal Register** titled, ''Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (84 FR 34478), referred to herein as the ''Specialty Care Models proposed rule,'' CMS proposed to include the rate of transplants, both living and deceased donor transplants, in the numerator for the ETC Model's transplant rate. However, in the Specialty Care Models final rule, we recognized the limitations of supply of deceased donor organs and updated the transplant rate to be calculated as the sum of the transplant waitlist rate and the living donor transplant rate (85 FR 61310). We stated that though a transplant is often the best treatment for a beneficiary with ESRD, in light of the current shortage of deceased donor organs for transplant, the transplant

waitlist rate and living donor transplant rate are currently more within the control of an ETC Participant (85 FR 61309).

However, in the Specialty Care Models final rule, we indicated our intent to observe the supply of deceased donor organs available for transplantation, with the goal of potentially modifying the transplant rate calculation for the future (85 FR 61309). Since the Specialty Care Models final rule was published on September 29, 2020, there have been several initiatives pursued by the Federal Government that could potentially have the effect of increasing the supply of both living donor organs and deceased donor organs.

On September 22, 2020, the Health Resources and Services Administration (HRSA) published a final rule in the **Federal Register** titled ''Removing Financial Disincentives to Living Organ Donation'' (85 FR 59438). This rule removes financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages, and child-care and elder-care expenses incurred by a caregiver. The rule went into effect on October 22, 2020.

Additionally, on December 2, 2020, CMS published in the **Federal Register** 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), revising Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs). The final rule revised the CfCs for OPOs in order to increase donation rates and organ transplantation rates and replaced the old outcome measures with new transparent, reliable, and objective measures. The final rule went into effect on March 30, 2021. The new outcome measures will be implemented for the recertification cycle beginning in 2022 and ending in 2026. The goals of this rule are complementary to the goals of the ETC Model, as the revised CfCs are intended to increase the supply of organs, and the ETC Model is designed to incentivize higher rates of transplantation.

Finally, as described in the Specialty Care Models final rule, CMS is in the process of implementing the ETC Learning Collaborative (85 FR 61346). The ETC Learning Collaborative is a voluntary learning system focused on increasing the availability of deceased donor kidneys for transplantation. The ETC Learning Collaborative works with and supports ETC Participants and other stakeholders required for successful kidney transplantation, such as transplant centers, OPOs, and large donor hospitals. CMS is currently in the process of jointly implementing the ETC Learning Collaborative with HRSA.

We are pleased that these efforts have progressed since the publication of the Specialty Care Models final rule. However, given that these efforts are still in the implementation process, we stated in the CY 2022 ESRD PPS proposed rule that we do not believe it would be appropriate to update the transplant rate to include accountability for deceased donor transplants, rather than transplant waitlisting, at this time (86 FR 36380). We further stated that we still intend to update the transplant rate through future rulemaking to include accountability for deceased donor transplants, but we are not proposing to do so at this time.

The following is a summary of the comments received on the status of organ availability and related topics and our responses.

Comment: Multiple commenters expressed support for continuing to monitor the transplant rate for ETC Participants based on transplant waitlisting, rather than updating the transplant rate to include accountability for deceased donor transplants.

Response: We appreciate the support and will continue to monitor organ supply, with the goal of eventually including accountability for deceased donor transplants through future rulemaking.

Comment: One commenter stated that an artificial kidney would have the best outcomes for transplant recipients and supports continued research towards the development of an artificial kidney.

Response: We agree that the creation of an artificial kidney could have clinical benefits for beneficiaries. To assist in the development of new technologies such as an artificial kidney, HHS is part of the KidneyX public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. More information on the KidneyX initiative is available at *kidneyx.org*.

Comment: One commenter stated that we should create a larger model that includes other key actors in the transplant process, including organ procurement organizations and transplant centers.

Response: We appreciate the feedback and will keep it in mind as we think about designing future models for testing. We view the ETC Model, including its ETC Learning Collaborative, as complementary to other efforts around the Department related to increasing the number of transplants, including the Kidney Care Choices Model, the OPO Conditions for Coverage updates (85 FR 77898), and the HRSA rule on Removing Financial Disincentives to Living Organ Donation (85 FR 59438). We will evaluate the ETC Model's interventions in the context of the effects of existing regulatory initiatives, but we may also consider a larger transplant model in the future.

Comment: One commenter suggested that we measure the number of beneficiaries referred for transplant rather than the length of time a beneficiary is on the transplant waitlist.

Response: In the Specialty Care Models final rule (85 FR 61310), we recognized the limitations of supply of deceased donor organs and updated the transplant rate to be calculated as the sum of the transplant waitlist rate and the living donor transplant rate. We selected the transplant waitlist rate specifically because inclusion on the waitlist was more within the control of the ETC Participant. While we did not discuss the possibility of referrals for transplant in the Specialty Care Models final rule, we believe that referrals for transplant is one step further removed from the actual receipt of a transplant relative to the beneficiary's inclusion on the transplant waitlist. A measure based on referrals would be operationally burdensome for CMS to collect and for ETC Participants to report. Additionally, such a measure would seem to have the potential for gaming, as ETC Participants could be incentivized to submit numerous referrals for individuals who would not qualify for inclusion on the transplant waitlist, or even for individuals previously denied inclusion. Accordingly, we are not adopting the commenter's suggestion at this time.

Comment: One commenter suggested that CMS establish new metrics for transplant providers, under the ETC Model, similar to the CMS quality measures published for ESRD facilities, as transplant providers play a large role in transplantation. One other commenter suggested that CMS establish a payment adjustment for transplant personnel to conduct transplant-related education activities in order to provide more accurate details about transplant to beneficiaries.

Response: At this time, we are not contemplating incorporating additional participant types, such as transplant providers, into the ETC Model. Accordingly, we are not adding quality measures or payment adjustments for transplant personnel, into the Model in this final rule. However, we appreciate

the feedback and suggestions, which we may use to inform future model design.

b. Beneficiary Exclusions From the Transplant Rate

As we discussed in the Specialty Care Models final rule (85 FR 61300), CMS received comments about excluding ESRD Beneficiaries with cancer from attribution to ETC Participants, as there was concern about treatment appropriateness. However, at that time, CMS did not have any evidence to suggest that this is a concern. Accordingly, we did not exclude beneficiaries with cancer from attribution to ETC Participants for purposes of calculating the home dialysis rate or the transplant rate in the Specialty Care Models final rule.

Nevertheless, as described in the CY 2022 ESRD PPS proposed rule (86 FR 36380), after we published the Specialty Care Models final rule, we conducted further analysis, to determine if a difference existed in either the home dialysis rate or transplant rate in beneficiaries with cancer and beneficiaries without cancer. Using the Medicare claims data and input from clinical specialists in the field of nephrology, we found that the majority of ESRD Beneficiaries with cancer, specifically ESRD Beneficiaries with cancer in vital solid organs (heart, lung, liver, and kidney), are not considered to be eligible candidates for transplant. Many transplant centers do not consider these beneficiaries for transplant and require them to be cancer-free for a specific period of time prior to assessing their eligibility for transplant. This is true for getting on a transplant waitlist and for receiving living donor transplants, as a beneficiary either needs to be cancer-free or be in an initial stage of cancer diagnosis to be considered for transplant.

In addition, we found that ESRD Beneficiaries who have a diagnosis of solid organ cancer for which they were receiving treatment, specifically radiation or chemotherapy, are less likely to be in the numerator of the transplant rate—so, being placed on the transplant waitlist or receive a living donor transplant—than ESRD Beneficiaries without a diagnosis of vital solid organ cancer. By contrast, we did not find any evidence to suggest that ESRD Beneficiaries with cancer had a significant difference in the home dialysis rate compared to the ESRD Beneficiaries without cancer.

As noted previously, under §§ 512.310 and 512.365(c), the transplant rate has two components: The transplant waitlist rate and the living donor transplant rate. Upon further review and analysis, beginning for MY3, we proposed to exclude ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries who have been diagnosed with vital solid organ cancers (heart, lung, liver, and kidney) and who are receiving treatment, in the form of radiation or chemotherapy, for such cancers from both components of the denominator of the transplant rate for both ESRD facilities and Managing Clinicians for the duration of the MY.

Furthermore, we proposed to include a lookback period, a period of time prior to the MY, to appropriately identify the ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries with a diagnosis of vital solid organ cancer for which they are receiving chemotherapy or radiation therapy. Both a diagnosis code and a treatment code are necessary to appropriately identify an ESRD Beneficiary or Pre-emptive LDT Beneficiary with a vital solid organ cancer who is receiving treatment with either radiation or chemotherapy. However, through our analysis we have identified beneficiaries who have only a treatment code available during the MY and do not have a diagnosis code during that period. Hence, we proposed to include a lookback period of 6-months prior to the MY, so that the appropriate diagnosis code can be identified for ESRD Beneficiaries and Pre-emptive LDT Beneficiaries who have only treatment codes available in the current MY. In the alternative, we considered a 12-month lookback period, but did not find any significant difference in the number of ESRD Beneficiaries and Pre-emptive LDT Beneficiaries that had a diagnosis code for a vital organ solid cancer during a 12-month lookback period as compared to a 6-month lookback period.

We proposed to identify ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries with a diagnosis of vital solid organ cancer and receiving treatment with radiation or chemotherapy by using Medicare claims. For purposes of the transplant rate calculations, we proposed that an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to have a diagnosis of vital solid cancer during the MY, if the ESRD Beneficiary has a claim with one of the following ICD–10 diagnosis codes:

- C22.0–C22.9 (malignant neoplasm of liver and intrahepatic bile ducts),
- C34.10–C34.12 (malignant neoplasm of upper lobe, bronchus or lung),
- C34.2 (malignant neoplasm of middle lobe, bronchus or lung),
- C34.30–C34.32 (malignant neoplasm of lower lobe, bronchus or lung),
- C34.80–C34.82 (malignant neoplasm of overlapping sites of bronchus and lung),
- C34.90–C34.92 (malignant neoplasm of unspecified part of bronchus or lung),
- C38.0 (malignant neoplasm of heart),
- C38.8 (malignant neoplasm of overlapping sites of heart, mediastinum and pleura),
- C46.50–C46.52 (Kaposi's sarcoma of lung),
- C64.1, C64.2, C64.9 (malignant neoplasm of kidney, except renal pelvis),
- C78.00–C78.02 (secondary malignant neoplasm of lung),
- C78.7 (secondary malignant neoplasm of liver and intrahepatic bile duct),
- C79.00–C79.02 (secondary malignant neoplasm of kidney and renal pelvis),
- C7A.090 (malignant carcinoid tumor of the bronchus and lung),
- C7A.093 (malignant carcinoid tumor of the kidney), or
- C7B.02 (secondary carcinoid tumors of liver).

We proposed that for the purposes of the transplant rate calculations, an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to be receiving treatment for vital solid organ cancer with either chemotherapy or radiation in the MY if the ESRD Beneficiary or Pre-emptive LDT Beneficiary has a claim with one of the following codes:

- CPT® 96401–96402, 96405–96406, 96409, 96411, 96413, 96415–96417, 96420, 96422–26423, 96425, 96440, 96446 (chemotherapy administration);
- CPT® 96549 (unlisted chemotherapy procedure);
- CPT® 77373 (stereotactic body radiation therapy);
- CPT® 77401–77402, 77407, 77412 (radiation treatment delivery);
- CPT® 77423 (high energy neutron radiation treatment delivery);
- CPT® 77424–77425 (Intraoperative radiation treatment delivery);
- CPT® 77520, 77522–77523, 77525 (proton treatment delivery);
- CPT® 77761–77763 (intracavitary radiation source application);
- CPT® 77770–77772, 77778, 77789, 77799 (clinical brachytherapy radiation treatment);
- CPT® 79005, 79101, 79200, 79300, 79403, 79440, 79445, 79999 (radiopharmaceutical therapy);
- ICD–10–PCS DB020ZZ, DB021ZZ, DB022ZZ, DB023Z0, DB023ZZ,

DB024ZZ, DB025ZZ, DB026ZZ, DB1297Z, DB1298Z, DB1299Z, DB129BZ, DB129CZ, DB129YZ, DB12B6Z, DB12B7Z, DB12B8Z, DB12B9Z, DB12BB1, DB12BBZ, DB12BCZ, DB12BYZ, DB22DZZ, DB22HZZ, DB22JZZ, DBY27ZZ, DBY28ZZ, DBY2FZZ, DBY2KZZ (radiation of lung);

- ICD–10–PCS DB070ZZ, DB071ZZ, DB072ZZ, DB073Z0, DB073ZZ, DB074ZZ, DB075ZZ, DB076ZZ, DB1797Z, DB1798Z, DB1799Z, DB179BZ, DB179CZ, DB179YZ, DB17B6Z, DB17B7Z, DB17B8Z, DB17B9Z, DB17BB1, DB17BBZ, DB17BCZ, DB17BYZ, DB27DZZ, DB27HZZ, DB27JZZ, DBY77ZZ, DBY78ZZ, DBY7FZZ, DBY7KZZ (radiation of chest wall);
- ICD–10–PCS DF000ZZ, DF001ZZ, DF002ZZ, DF003Z0, DF003ZZ, DF004ZZ, DF005ZZ, DF006ZZ, DF1097Z, DF1098Z, DF1099Z, DF109BZ, DF109CZ, DF109YZ, DF10B6Z, DF10B7Z, DF10B8Z, DF10B9Z, DF10BB1, DF10BBZ, DF10BCZ, DF10BYZ, DF0DZZ, DF20HZZ, DF20JZZ, DFY07ZZ, DFY08ZZ, DFY0CZZ, DFY0FZZ, DFY0KZZ (radiation of liver);
- ICD–10–PCS DT000ZZ, DT001ZZ, DT002ZZ, DT003Z0, DT003ZZ, DT004ZZ, DT005ZZ, DT006ZZ, DT1097Z, DT1098Z, DT1099Z, DT109BZ, DT109CZ, DT109YZ, DT10B6Z, DT10B7Z, DT10B8Z, DT10B9Z, DT10BB1, DT10BBZ, DT10BCZ, DT10BYZ, DT20DZZ, DT20HZZ, DT20JZZ, DTY07ZZ, DTY08ZZ, DTY0CZZ, DTY0FZZ (radiation of kidney);
- ICD–10–PCS DW020ZZ, DW021ZZ, DW022ZZ, DW023Z0, DW023ZZ, DW024ZZ, DW025ZZ, DW026ZZ, DW1297Z, DW1298Z, DW1299Z, DW129BZ, DW129CZ, DW129YZ, DW12B6Z, DW12B7Z, DW12B8Z, DW12B9Z, DW12BB1, DW12BBZ, DW12BCZ, DW12BYZ, DW22DZZ, DW22HZZ, DW22JZZ, DWY27ZZ, DWY28ZZ, DWY2FZZ (radiation of chest); or
- ICD–10–PCS DW030ZZ, DW031ZZ, DW032ZZ, DW033Z0, DW033ZZ, DW034ZZ, DW035ZZ, DW036ZZ, DW1397Z, DW1398Z, DW1399Z, DW139BZ, DW139CZ, DW139YZ, DW13B6Z, DW13B7Z, DW13B8Z, DW13B9Z, DW13BB1, DW13BBZ, DW13BCZ, DB13BYZ, DW23DZZ, DW23HZZ, DW23JZZ, DWY37ZZ, DWY38ZZ, DWY3FZZ (radiation of abdomen).

We sought comment on the proposal to amend § 512.365(c) to exclude ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries with a diagnosis of vital solid organ cancer and receiving treatment with chemotherapy or radiation from the denominator of the transplant rate as a whole, including both the transplant waitlist rate component and the living donor transplant rate component, for the duration of the MY for both ESRD facilities and Managing Clinicians.

The following is a summary of the comments received on the proposal to exclude ESRD beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, with a diagnosis of vital solid organ cancer and receiving treatment with chemotherapy or radiation from the denominator of the transplant rate for the duration of the MY, beginning for MY3, and our responses.

Comment: Several commenters stated they agree with the proposal to exclude beneficiaries, including Pre-emptive LDT Beneficiaries, with vital solid organ (heart, liver, lung, and kidney) cancers from the denominator of the transplant rate. The majority of these commenters also agreed with our proposal to use a six-month lookback period to identify these beneficiaries.

Response: We appreciate the commenters' support.

Comment: Several commenters suggested that CMS exclude additional beneficiaries from the transplant rate based on one or more criteria. A few of these commenters suggested that CMS exclude beneficiaries with all cancers, while one of the commenters suggested specific additional cancers. Another commenter suggested that CMS add breast cancer to the list of cancer exclusions, if CMS does not exclude beneficiaries with all cancers. Another commenter, suggested that CMS exclude beneficiaries with all active malignancies.

Response: In response to the commenters' suggestions to exclude beneficiaries with additional cancers, all active malignancies, or all cancers from the transplant rate, we recognize that transplant centers may vary in the cancers used to determine eligibility for transplant. However, having cancer may not automatically eliminate a beneficiary from being eligible for transplant. As noted in the proposed rule (86 FR 36380), our internal analysis identified that ESRD Beneficiaries with cancer in vital solid organs (heart, kidney, liver, lung) for which they are receiving treatment with radiation or chemotherapy, are less likely to be in the numerator of the transplant rate—so being placed on the transplant waitlist or receiving a living donor transplant—than ESRD Beneficiaries without a diagnosis of vital solid organ cancer. As noted in the Specialty Care Models final rule (85 FR 61301), CMS would like to encourage ETC Participants to provide home dialysis and transplantation for as many beneficiaries that would benefit from these care modalities. Accordingly, we are excluding from the transplant rate calculation only those beneficiaries who are particularly unlikely to be eligible for transplants; specifically, those beneficiaries with vital solid organ cancers who are receiving treatment through radiation or chemotherapy.

Comment: One commenter suggested that CMS exclude all beneficiaries who have untreatable cardiopulmonary, cardiovascular, peripheral vascular disease, significant physical disability (Karnofsky Score <40 percent), severe pulmonary issues, severe morbid obesity (BMI >50), or recurrent chronic infections. In addition, other commenters suggested that we exclude beneficiaries with end-stage Chronic Obstructive Pulmonary Disease (COPD) and diagnoses involving heart failure.

Response: As noted above, transplant centers have varying criteria when considering a beneficiary as eligible for transplant. For instance, many transplant centers do not reject a beneficiary for transplant solely on the basis of the non-cancer conditions suggested by commenters. Thus, the general categorization of these conditions for exclusion is not appropriate. Moreover, as noted previously, CMS would like to encourage ETC Participants to provide home dialysis and transplantation for as many beneficiaries that would benefit from these care modalities; our ability to achieve this aim would be compromised were CMS to exclude too many categories of beneficiaries from the Model's financial calculations. Accordingly, we are not adding these conditions for beneficiary exclusion from the transplant rate at this time. Nonetheless, we will continue to consider whether any additional conditions should be added to the exclusion criteria for transplant rate through future rulemaking.

Comment: One commenter suggested that CMS operationalize the exclusion of beneficiaries with cancer in vital solid organs from the transplant rate by using only diagnosis codes, rather than a combination of diagnosis codes and treatment codes, to identify such beneficiaries, as treatment might not have started or might not be appropriate.

Response: As we noted in the CY 2022 ESRD PPS proposed rule (86 FR 36380), we proposed to include a lookback period, a period of time prior to the MY, to appropriately identify beneficiaries with a diagnosis of a vital

solid organ cancer for which they are receiving treatment in light of internal analysis that identified beneficiaries who have a treatment code, but not a diagnosis code, during the MY. In order to capture the ESRD beneficiaries with the vital solid organ cancer diagnosis appropriately, we proposed to include a lookback period of 6 months. While we considered a 12-month lookback period, as noted in the CY 2022 ESRD PPS proposed rule (86 FR 36380), our internal analysis did not identify any significant difference in the number of beneficiaries that had a diagnosis for a vital solid organ cancer during a 12-month lookback period as compared to a 6-month lookback period. In addition, a longer lookback period was not considered to identify diagnosis code(s) as the exclusion is to identify beneficiaries with active cancer because our internal analysis did not identify any significant difference in the number of beneficiaries that had a diagnosis for a vital solid organ cancer during a lookback period longer than 12 months as compared to a 6-month lookback period. We therefore decline to adopt the commenter's suggestion of using a 2-year lookback period to identify cancer diagnosis.

In the CY 2022 ESRD PPS proposed rule (86 FR 36280), we did not propose a lookback period for treatment codes. However, CMS did previously identify beneficiaries with a diagnosis code and no treatment code during the MY. Given that several commenters suggested that CMS include a lookback period for treatment, and considering that a beneficiary could have ended their most recent course of treatment immediately prior to the start of a given MY, we are modifying our proposal to include a lookback period of 6-months to identify radiation or chemotherapy treatment codes for beneficiaries with diagnosis code of vital solid organ cancer during the MY, similar to the proposed lookback period for diagnosis codes that we are finalizing in this rule. We are limiting the lookback period to identify radiation or chemotherapy treatment code(s) to 6 months because the purpose of this particular exclusion is to exclude from the transplant rate beneficiaries who have an active cancer and are receiving treatment, as these beneficiaries are less likely to be placed on the transplant waitlist. Beneficiaries who received radiation or chemotherapy treatment greater than 6 months before the start of the MY are unlikely to be actively receiving treatment and thus do not need to be excluded from the transplant rate for that reason.

After considering the comments received, we are finalizing a 6-month lookback period, as proposed, for identifying a vital solid organ cancer diagnosis code for beneficiaries who have only a treatment code during the MY. In addition, we are adding in a 6-month lookback period for identifying radiation and chemotherapy treatment codes for beneficiaries who have only a diagnosis code during the MY.

Final Rule Action: After considering public comments, we are finalizing our proposal with modification. First, we are amending our regulation at § 512.365(c) to exclude ESRD beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who had a diagnosis of vital solid organ cancer and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY from the denominator of the transplant rate calculation, beginning for MY3. Second, we are making two modifications to correct the information included in the proposed rule (86 FR 36380–36381). Specifically, we are clarifying the list of ICD–10 diagnosis codes included in § 512.365(c)(1)(i)(A)(*1*) to replace ''C22.1–C22.9,'' with ''C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8 and C22.9.'' The codes C22.1–C22.9 are not sequential—that is, there is no C22.5 or C22.6—and therefore should not have been grouped. In addition, while we referenced C22.0 in the preamble of the CY 2022 ESRD PPS proposed rule, this code was left out of the proposed regulation text in error. C22.2 was also left out of the proposed regulation text in error. In addition, we are also modifying the list of treatment codes at § 512.365(c)(1)(i)(A)(*2*)(*ii*) to correct a typo of the ICD–10–PCS codes from ''DF0DZZ,'' to ''DF20DZZ,'' which refers to radiation of the liver. Third, we are adding a 6-month lookback period to identify radiation and chemotherapy treatment codes for beneficiaries who only have a vital solid organ cancer diagnosis code during the MY.

5. PPA Achievement Benchmarking

a. Background on Achievement Benchmarking

Under the ETC Model, the PPA is a positive or negative adjustment on dialysis and dialysis-related Medicare payments, for both home dialysis and in-center dialysis. To calculate an ETC Participant's PPA, we assess ETC Participant achievement on the home dialysis rate and transplant rate in relation to achievement and improvement benchmarks, as described in 42 CFR 512.370(b) and § 512.370(c), respectively. The Model more heavily weights achievement of results, allowing participating Managing Clinicians or ESRD facilities to earn up to 2 points in the scoring methodology, as opposed to only 1.5 points for maximum level of improvement, as described in §§ 512.370(b) and 512.370(c).

The achievement benchmarks are constructed based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during corresponding Benchmark Years. Achievement benchmarks are percentile based, and an ETC Participant receives the achievement points that correspond with its performance, at the aggregation group level, on the home dialysis rate and transplant rate in relation to the achievement benchmarks, as described in § 512.370(b). Table 7 details the achievement score scale described in § 512.370(b).

TABLE 7: Current Scoring Methodology for Achievement Scores

Achievement Score Scale for MY1 and MY2	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.5
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	0

In the Specialty Care Models proposed rule, we proposed to apply this achievement benchmark policy only for MY1 and MY2, and stated our intent to increase achievement benchmarks for ETC Participants above the rates observed in Comparison Geographic Areas. We stated our belief that increasing the achievement benchmarks for future MYs, which we would do through subsequent rulemaking, was necessary in order to provide sufficient incentive for ETC Participants to increase rates of home dialysis and transplantation at a rate faster than would occur absent the ETC Model (84 FR 34556 through 34557). In the Specialty Care Models final rule, in response to comments, we finalized the applicability of the achievement benchmarks for MY1 through MY2 and for subsequent MYs (85 FR 61323), but reiterated our intent to establish a different method for establishing achievement benchmarks for future years of the Model through subsequent rulemaking (85 FR 61320). We stated our belief that future modifications to the achievement benchmark methodology finalized in the Specialty Care Models final rule would be necessary to provide sufficient incentive for ETC Participants to raise home dialysis and transplant rates at a rate faster than would occur absent the ETC Model (85 FR 61321). However, we clarified that while we had stated a goal of 80 percent of an ETC Participant's receiving home dialysis or a transplant in order to receive the maximum upward payment adjustment by the final MYs, we were not finalizing that goal in the Specialty Care Models final rule (85 FR 61321).

b. Addressing Socioeconomic Factors That Impact ETC Participant Achievement

In the Specialty Care Models final rule, we acknowledged commenters' concerns that non-clinical factors, such as socioeconomic status, may impact a beneficiary's likelihood to receive home dialysis or transplant. We discussed commenters' suggestions to incorporate consideration of socioeconomic status in two elements of the ETC Model: (1) Beneficiary attribution; and (2) risk adjustment. However, we declined to exclude beneficiaries from attribution based on socioeconomic status. Noting the importance of not excluding these beneficiaries, CMS stated its intent to assess the use of various codes for purposes of adding any additional beneficiary exclusions from attribution to ETC Participants based on socioeconomic status, homelessness, or other social determinants of health through future rulemaking (85 FR 61299). We also noted that commenters' suggestions for ways to risk adjust the home dialysis rate based on socioeconomic status were a significant departure from the policy originally proposed (85 FR 61315).

In the CY 2022 ESRD PPS proposed rule (86 FR 36382), we continued to acknowledge the impact that non-clinical factors, such as socioeconomic status, have on a beneficiary's likelihood to receive home dialysis or a transplant. Our additional analysis of Medicare claims data shows that beneficiaries who are dual-eligible for Medicare and Medicaid or receive the Medicare Low-Income Subsidy (LIS) are less likely than beneficiaries who are not dual-eligible and are not LIS recipients to dialyze at home or to receive a kidney transplant. As such, ETC Participants who have a higher proportion of attributed beneficiaries who are dual-eligible or LIS recipients may be less likely to achieve high home dialysis and transplant rates than ETC Participants who have a lower proportion of attributed beneficiaries who are dual-eligible or LIS recipients.

c. Achievement Benchmarking and Scoring

(1) Achievement Benchmarking and Scoring for MY3 Through MY10

We proposed to modify the percentile-based achievement benchmarking methodology based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year as the basis for achievement benchmarks in MY3 through MY10 (86 FR 36382). Rather than using rates observed in Comparison Geographic Areas, we proposed to modify § 512.370(b)(1) to use rates observed in Comparison Geographic Areas as the base for the achievement benchmarks, and to increase the achievement benchmarks above the Comparison Geographic Area rates during the Benchmark Year by 10 percent every two MYs, beginning for MY3. As such, we proposed that achievement benchmarks would be calculated by multiplying the percentile rate observed in Comparison Geographic Areas during the Benchmark Year by 1.1 for MY3 and MY4, by 1.2 for MY5 and MY6, by 1.3 for MY7 and MY8, and by 1.4 for MY9 and MY10.

Based on our analyses detailed in the CY 2022 ESRD PPS proposed rule and in section VIII.C.4 of this final rule, this proposed methodology for increasing benchmarks by 10 percent every two MYs would produce results in keeping with the initial impact estimates for the ETC Model, as described in the Specialty Care Models final rule (85 FR 61353 through 61354). In the Specialty Care Models final rule, we estimated impacts based on projected growth rates for the home dialysis and transplant rates based on historical observation, projected a 1.5 percentage point growth rate (86 FR 36383). In the CY 2022 ESRD PPS proposed rule and in section VIII.C.4 of this final rule, updated projections assume the same projected growth rate, but note that observed rates of increase have accelerated in more recent data. As such, in the CY 2022

ESRD PPS proposed rule we stated our belief that this rate of increase would be attainable for ETC Participants, as initial impact estimates were based on rates of increase observed on the home dialysis rate and transplant rate before the ETC Model began (85 FR 61353). We also noted that, unlike in the Specialty Care Models proposed rule (84 FR 34556), we were not proposing to increase achievement benchmarks such that of 80 percent of an ETC Participant's attributed beneficiaries would need to be receiving home dialysis or a transplant in order for the ETC Participant to receive the maximum upward payment adjustment by the final MYs. Table 8 details the proposed scoring methodology for assessment of MY3 through MY10 achievement scores.

TABLE 8: Proposed Scoring Methodology for Assessment of Measurement Years 3 through 10 Achievement Scores on the Home Dialysis Rate and Transplant Rate

Achievement Score Scale				Points
MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	
1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	2
1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.5
1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1
1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	0.5
1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	0

In the CY 2022 ESRD PPS proposed rule, we considered increasing achievement benchmarks by a percentage point amount, rather than by a percent amount, every two MYs (for example, increasing achievement benchmarks by 10-percentage points for MY3 and MY4, by 20-percentage points for MY5 and MY6, etc.). However, we stated our belief that this percentage point-based approach would be less flexible to and accommodating of variation in the underlying distributions of home dialysis and transplant rates than the percent-based approach we are proposing. We also stated our belief that this percentage point-based approach would add additional complexity, as we would likely need to develop separate percentage point amounts by which to increase benchmarks as the home dialysis rate and transplant rate observed in Comparison Geographic Areas are not sufficiently similar to expect the same percentage point growth rate for the two rates.

In the CY 2022 ESRD PPS proposed rule, we also considered proposing to modify the Benchmark Year, such that the Benchmark Year would be a fixed duration (for example, July 1, 2018 through June 30, 2019), rather than a period of time defined in relation to the relevant MY. However, we determined that this approach would not account for aggregate changes in the home dialysis rate and transplant rate over time.

In the CY 2022 ESRD PPS proposed rule we stated our belief that the proposed approach for increasing achievement benchmarks over the course of the ETC Model would balance the intent of the model design to increase rates of home dialysis and transplantation above what would have occurred in the absence of the Model with what is achievable for ETC Participants, based on rates of home dialysis and transplantation observed at the high ends of the distributions (for additional discussion, see 86 FR 36427). We also stated our belief that the proposed approach would provide

clarity to ETC Participants about the benchmarking methodology for the duration of the ETC Model while maintaining flexibility in that methodology to address long term trends in the home dialysis rate and transplant rate.

We sought public comment on our proposal to modify the achievement benchmarking methodology under § 512.370(b) beginning for MY3 to increase achievement benchmarks, and the proposal to increase achievement benchmarks by 10 percent every two MYs above percentile-based rates of observed in Comparison Geographic Areas.

The following is a summary of the comments received on our proposal to modify the achievement benchmarking methodology beginning for MY3 to increase achievement benchmarks by 10 percent every two MYs above rates observed in Comparison Geographic Areas, and our responses.

Comment: Many commenters stated that they support increasing achievement benchmarks over the duration of the ETC Model.

Response: We appreciate the support for increasing the PPA achievement benchmarks throughout the duration of the ETC Model.

Comment: Two commenters opposed increasing achievement benchmarks over time. One such commenter stated that the increasing magnitude of the PPA, and the use of improvement scoring, collectively create a sufficient incentive for ETC Participants to continue to increase rates of home dialysis and transplant. The other such commenter stated that they opposed increasing achievement benchmarks over time, as doing so will ensure that ETC Participants cannot be successful in the ETC Model, resulting in payment cuts.

Response: In response to the comment that the increasing magnitude of the PPA and use of improvement scoring create a sufficient incentive to promote continued increases in rates of home dialysis and transplant, we disagree that these two factors alone are sufficient. As such, we believe it is necessary to increase achievement benchmarks over the course of the ETC Model. Similarly, we disagree with the commenter that increasing achievement benchmarks will result in payment cuts for all ETC Participants. While we project that the ETC Model will reduce Medicare expenditures, ETC Participants can still earn positive payment adjustments through their performance in the Model.

Comment: Several commenters stated that they appreciate and support that CMS is establishing the achievement benchmarking methodology for the remaining years of the Model through this rulemaking.

Response: As stated in the Specialty Care Models final rule (85 FR 61321), we believe that establishing changes to the achievement benchmarking methodologies for subsequent MYs through notice-and-comment rulemaking is transparent and will provide sufficient notice to ETC Participants to plan for the updated achievement benchmarking methodology.

Comment: Several commenters stated that CMS should ensure that achievement benchmarks are achievable for ETC Participants.

Response: We agree that the achievement benchmarks should be achievable, while ensuring that there is sufficient incentive for ETC Participants to continue to increase rates of home dialysis and transplantation through the duration of the Model. As discussed in the CY 2022 ESRD PPS proposed rule and section V.B.5.c.(1) of this final rule, we believe that the achievement benchmarking methodology we are finalizing is achievable.

Comment: Several commenters stated that they agree with the proposal to increase achievement benchmarks by 10 percent every two MYs. One of these commenters stated that this increase is necessary to sustain continued growth in the home dialysis rate and transplant rate.

Response: We appreciate the commenters' support for increasing benchmarks by 10 percent every two MYs. We agree that this increase is necessary to sustain continued growth in rates of home dialysis and transplantation in the ETC Model.

Comment: A few commenters stated that increasing the home dialysis rate by 10 percent is, or may be, achievable based on growth in home dialysis rates observed in 2019, 2020, and 2021.

Response: We appreciate commenters' statements that a 10 percent increase in the home dialysis rate is or may be achievable for ETC Participants. We agree that a 10 percent increase is achievable for ETC Participants based on recent historical growth rates. Specifically, in the Specialty Care Models final rule (85 FR 61354), we projected a 1.5 percentage point growth rate in the home dialysis and transplant rates. While the updated projections in the CY 2022 ESRD PPS proposed rule and in section VIII.C.4 of this final rule assume the same projected growth rate, initial impact estimates were based on rates of increase observed on the home dialysis rate and transplant rate before the ETC Model began and observed rates of increase have accelerated in more recent data.

Comment: Several commenters stated that CMS should not increase achievement benchmarks by 10 percent every two MYs. Some such commenters stated that 10 percent is an arbitrary amount, that 10 percent is too large, and that 10 percent is not achievable. As evidence that a 10 percent increase in achievement benchmarks every two MYs is not achievable, one such commenter pointed to the lack of growth in home dialysis observed as a result of the shift to the ESRD PPS bundled payment system in 2011, and between 2018 and 2021, and that transplant waitlist rates were relatively stable between 2014 and 2019. Another commenter, who is a dialysis provider, stated that 10 percent home dialysis growth is not consistent with their own growth rate over the past year.

Response: We disagree with commenters that a 10 percent increase in the achievement benchmarks every two MYs is not attainable, as we believe that 10 percent is neither too large nor not achievable. We also disagree that a 10 percent increase is arbitrary. As stated in the CY 2022 ESRD PPS proposed rule and in sections V.B.5.c.(1) and VIII.C.5.d.(10) of this final rule, we selected 10 percent based on analysis of historical observations, attainability, transparency for ETC Participants, and the need to preserve the expectation for model net savings. We have also noted, as did a few commenters, that in the recent years these observed rates of increase in the home dialysis rate and transplant rate have accelerated and as such we continue to believe the proposed rate of increase would be attainable for ETC Participants.

In regards to the home dialysis rate specifically, CMS acknowledges the lack of growth in home dialysis observed following the shift to the ESRD PPS bundled payment system in 2011. Indeed, as described in the Specialty Care Models final rule (85 FR 61273), while CMS has undertaken previous efforts expected to increase rates of home dialysis, low rates of home dialysis have persisted. Therefore, the ETC Model was designed to test the effectiveness of more significant incentives to increase rates of home dialysis by tying payment incentives directly to increasing rates of home dialysis. However, we disagree with the commenter that stated that home dialysis rates have not grown in recent years. Prior to the announcement of the ETC Model in 2019, the home dialysis rate increased by 7.9 percent among prevalent patients with ESRD from 2017

to 2018.[274] More recently, as described in section VIII.C.5.d.(3) of this final rule, the aggregate home dialysis rate grew by approximately 4 percent in CY 2020. Regarding the commenter who stated that 10 percent was not consistent with their own historical growth rate for home dialysis, we have not asserted that any individual dialysis provider has experienced this growth rate, nor do we expect any individual dialysis provider's experience prior to the ETC Model to be representative of future potential growth in home dialysis rates for all ETC Participants. Instead, we have set the 10 percent increase in the achievement benchmark based on projected growth rates in home dialysis and transplant, based on historical observations, and we believe that a 10-percent increase will be attainable for ETC Participants.

Regarding the transplant rate specifically, we acknowledge that the transplant waitlist rates were stable between 2014 and 2019, as noted by the commenter. However, CMS and HHS are undertaking a number of efforts regarding transplantation, as we described in the CY 2022 ESRD PPS proposed rule and in section V.B.4.a of this final rule. This coordinated effort around transplant availability did not exist prior to 2019, and we believe that this effort will facilitate increasing rates of transplantation during the remaining MYs of the ETC Model.

Comment: One commenter stated that if CMS increases achievement benchmarks as proposed, it should do so only for ESRD facilities owned by LDOs, as the commenter is concerned about the ability of ESRD facilities not owned by LDOs to increase their home dialysis and transplant rates.

Response: We disagree with the commenter that CMS should increase achievement benchmarks only for ESRD facilities owned by LDOs. As discussed in the Specialty Care Models final rule (85 FR 61284), the ETC Model is designed to test the effectiveness of using payment adjustments to maintain or improve quality while decreasing costs by increasing rates of home dialysis and transplants for all types of ESRD facilities nationally, including those owned by both large and small dialysis organizations. To determine if payment adjustments can achieve the Model's goals of increasing rates of home dialysis utilization and kidney transplant and, as a result, improving or maintaining the quality of care while reducing Medicare expenditures among all types of ESRD facilities, we need to test the model with ESRD facilities owned by all types of dialysis organizations. By extension, we believe that it is necessary to increase the achievement benchmarks in a consistent manner for all ESRD facilities participating in the ETC Model, regardless of type of ownership, to create the same incentives for all ESRD facilities to increase rates of home dialysis and transplants. Using the same achievement benchmarks also increases the generalizability of the ETC Model results.

Comment: A few commenters stated that they agreed with the proposal to set achievement benchmarks in relation to rates observed in Comparison Geographic Areas.

Response: We appreciate commenters' support for setting achievement benchmarks in relation to rates observed in Comparison Geographic Areas.

Comment: Several commenters opposed setting achievement benchmarks in relation to rates observed in Comparison Geographic Areas. These commenters stated that basing benchmarks on BY rates in Comparison Geographic Areas may cause dialysis organizations with ESRD facilities to focus their resources on increasing rates in Selected Geographic Areas to the detriment of those in Comparison Geographic Areas. Similarly, these commenters, including LDOs, stated that this approach could create an opportunity for dialysis organizations with ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas to manipulate achievement benchmarks by keeping home dialysis and transplant rates artificially low in Comparison Geographic Areas. These commenters stated that any such gaming by dialysis organizations would be harmful to beneficiaries and would run counter to the intent of the ETC Model. Another commenter stated that this dynamic could disadvantage ESRD facilities not owned by LDOs, and further market consolidation. Several commenters stated that CMS should use ''absolute'' or ''fixed'' benchmarks, to avoid gaming opportunities by dialysis organizations with ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas. These commenters suggested setting fixed benchmarks based on rates observed in Comparison Geographic Areas during a fixed period of time, such as Benchmark Year 1, or based on historical rates observed in Selected Geographic Areas instead of Comparison Geographic Areas.

Response: We understand commenters' concerns that entities that own ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas may choose to engage in practices that limit the growth of home dialysis and transplantation in Comparison Geographic Areas, either because they are incentivized under the Model to focus on Selected Geographic Areas or because they seek to manipulate or ''game'' achievement benchmarks based on rates observed in Comparison Geographic Areas for financial gain.

The purpose of the ETC Model is to test whether the Model's payment adjustments will change the behavior of ETC Participants to increase rates of home dialysis and transplantation such that quality is maintained or improved while costs are reduced. If the Model test achieves these aims, we expect ETC Participants to behave differently than ESRD facilities and Managing Clinicians who are not ETC Participants. That is, we expect ETC Participants to respond to the Model's incentives to increase rates of home dialysis and transplantation over the course of the Model.

However, we do not expect or intend that testing the ETC Model will harm or disadvantage beneficiaries whose ESRD facilities and Managing Clinicians are not ETC Participants. First, there are a number of factors that mitigate the risk that ESRD facilities owned by entities operating in both Selected Geographic Areas and Comparison Geographic Areas can manipulate achievement benchmarks based on rates observed in Comparison Geographic Areas. For instance, organizations that own ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas do not have sole control over the rates of home dialysis, transplant waitlisting, or living donation in Comparison Geographic Areas. Each ESRD Beneficiary has a Managing Clinician who is responsible for managing their dialysis care, as well as other healthcare providers. Managing Clinicians, in particular, provide education about renal replacement options to ESRD Beneficiaries and Preemptive LDT Beneficiaries, and prescribe dialysis for ESRD Beneficiaries. Unlike ESRD facilities owned by organizations with ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas, few Managing Clinicians are in practices that operate in both Selected Geographic Areas and Comparison Geographic Areas, and as such are unlikely to even be able to provide differential care in different areas.

[274] United States Renal Data System. 2020. *2020 Annual Data Report.* ''Figure 1.13 Number of prevalent ESRD patneits performing home dialysis, 2000–2018.'' *https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities.*

Regarding the transplant rate in particular, we recognize that ESRD facilities play an important role in transplant waitlisting and living donor transplants. As ESRD Beneficiaries interact with their ESRD facility multiple times a week, ESRD facilities are well positioned to support beneficiaries through the transplant process. Additionally, ESRD facilities are required to conduct certain transplant-related activities for their patients, as described in 42 CFR 494.70, 494.80, and 494.90. However, an ESRD Beneficiary's Managing Clinician and other healthcare providers are equally important for supporting a beneficiary through the transplant process.

Regarding the home dialysis rate in particular, while we recognize that certain ESRD facilities located in both Selected Geographic Areas and Comparison Geographic Areas—namely those owned in whole or in part by LDOs—provide the majority of dialysis, they are not the sole providers of dialysis. Smaller chains and independent ESRD facilities, many of which do not operate in both Selected Geographic Areas and Comparison Geographic Areas, provide a significant volume of dialysis services and are less likely to face the incentive described by commenters to provide differential care in different areas, for either resource or gaming reasons. Additionally, if the demand for home dialysis increases but ESRD facilities owned by organizations that operate in both Selected Geographic Areas and Comparison Geographic Areas are unable or unwilling to increase the availability of home dialysis in Comparison Geographic Areas, ESRD facilities owned by smaller chains or independent ESRD facilities may be able to increase supply to meet the unmet demand in those areas.

Second, as described in the Specialty Care Models final rule (85 FR 61320), CMS will engage in active monitoring for adverse outcomes, including behavior described by commenters, and we intend to make adjustments to the Model through subsequent rulemaking should such unintended consequences arise. We also note that CMS may take remedial action under § 512.160 of our regulations if an ETC Participant fails to comply with any terms of the Model, including the provisions protecting beneficiary freedom of choice and availability of services under § 512.120 of our regulations, or if an ETC Participant has taken any action that threatens the health or safety of a beneficiary or other patient.

Taken together we believe that these factors, coupled with CMS's monitoring efforts and ability to take remedial action, mitigate the risk that entities that own ESRD facilities in both Selected Geographic Areas and Comparison Geographic areas will alter achievement benchmarks by manipulating rates in Comparison Geographic Areas.

Comment: A few commenters stated that CMS should use the methodology used to set the performance standards under the ESRD QIP for setting achievement benchmarks under the ETC Model. One such commenter stated that the ESRD QIP performance standard setting methodology is preferable to the achievement benchmarking approaches described in the CY 2022 ESRD PPS proposed rule because it would continue to incentivize improved performance while not relying on rates observed in Comparison Geographic Areas, and is simple and familiar to ESRD facilities. This commenter also stated that the ESRD QIP methodology was preferable because it does not allow performance standards to decrease over time.

Response: As stated in the Specialty Care Models final rule, we do not believe the ESRD QIP methodology is well suited for the ETC Model (85 FR 61322 through 61323). In particular, we continue to believe that the ESRD QIP performance standard setting methodology does not ensure escalating performance standards over time, which is an important design feature for the ETC Model. Similarly, we continue to recognize that, while ESRD facilities are familiar with the ESRD QIP performance standard setting methodology because they are already subject to it, Managing Clinicians are not.

Comment: A few commenters stated that CMS should use population-weighted achievement benchmarks, to account for variation in size among aggregation groups. One such commenter stated that population-weighted benchmarks are more appropriate because of the difference in absolute change necessary for larger and smaller aggregation groups to achieve the same relative performance. That is, relative to smaller aggregation groups, larger aggregation groups need to have a larger number of individual beneficiaries change from in-center dialysis to home dialysis, self-dialysis, or nocturnal in-center dialysis to increase their home dialysis rate; or to have a larger number of individual beneficiaries be waitlisted for transplant or receive a living donor transplant to increase their transplant rate to achieve the same level of performance. The commenter also stated that larger aggregation groups have a larger absolute impact on the number of beneficiaries who dialyze at home or are placed on the transplant waitlist, and therefore should not be compared to smaller aggregation groups who may have the same relative level of performance but a smaller absolute impact.

Response: We appreciate commenters' suggestion that we use population-weighted benchmarks. However, we did not propose this approach, and we are not contemplating this change at this time.

Additionally, we disagree with the commenter who stated that population-weighted benchmarks are more appropriate because larger aggregation groups need to increase rates of home dialysis, transplant waitlisting, and living donor transplants among a larger number of beneficiaries relative to smaller aggregation groups to achieve the same level of performance. We believe that that this approach would unfairly disadvantage smaller aggregation groups, holding them to a higher relative standard solely because they have fewer attributed beneficiary months. We also disagree that larger aggregation groups should be held to a lower relative standard than smaller aggregation groups because they have a larger absolute impact.

Comment: One commenter opposed the negative payment adjustments included in the ETC Model and suggested that the Model instead have only positive payment adjustments.

Response: As noted in the Specialty Care Models final rule (85 FR 61264), the purpose of the ETC Model is to test whether the payment adjustments included in the Model will reduce Medicare expenditures while improving or maintaining quality of care. As further stated in the Specialty Care Models final rule (85 FR 61323), we believe that downside risk is a critical component of this Model in order to create strong incentives for behavioral change among ETC Participants, that is by encouraging participating Managing Clinicians and ESRD facilities to support beneficiaries choosing home dialysis and transplantation. We therefore disagree that eliminating the negative adjustments would provide sufficient incentive to encourage behavior change leading to the achievement of the goals of the Model.

Comment: One commenter stated that, instead of increasing achievement benchmarks to increase rates of home dialysis and transplantation, CMS should instead focus on increasing participation in the ETC Model in more areas of the country, if the ETC Model is successful at increasing rates of home dialysis and transplantation.

Response: As described previously in section V.A.3 of this final rule, the purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. If the Model meets the criteria set forth in section 1115A(c) of the Act, we may consider expanding the duration and scope of the ETC Model. However, the Model calculates benchmarks and assesses ETC Participant performance against rates of home dialysis, transplant waitlisting, and living donor transplantation among similar Managing Clinicians or ESRD facilities located in Comparison Geographic Areas. A limitation on Model participation is therefore currently necessary to ensure there are sufficient comparators for these purposes.

Comment: One commenter stated that we should update the PPA methodology by increasing the weight of the transplant rate to be equal to the home dialysis rate, or by separating out the transplant rate completely so that one is not dependent on the other.

Response: As discussed in the Specialty Care Models final rule (85 FR 61319), CMS had considered making the home dialysis rate score and the transplant rate score equal components of the Modality Performance Score (MPS) used in calculating the PPA. However, we recognized that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers or suppliers that are part of the transplant process. For this reason, under the PPA methodology, home dialysis rates take a greater weight than transplant rates.

Comment: One commenter suggested that CMS modify the Model such that the MPS applies only to Managing Clinicians as, by the time a beneficiary begins dialysis with an ESRD facility, it is too late for the ESRD facility to encourage pre-emptive transplant and pre-emptive transplant recipients will see an ESRD facility only after a transplant rejection.

Response: We would like to clarify for the commenter that the MPS is calculated for all ETC Participants based on their home dialysis rate and transplant rate, in order to determine the ETC Participant's PPA. However, the pre-emptive transplant rate is part of the transplant rate calculation only for Managing Clinicians.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.370(b) to increase achievement benchmarks by 10 percent every two MYs above rates observed in Comparison Geographic Areas, as proposed.

(2) Achievement Benchmark Stratification by Dual-Eligible and Low Income Subsidy (LIS) Status

We also proposed to modify § 512.370(b) to stratify achievement benchmarks based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries were dually-eligible for Medicare and Medicaid or received the LIS, based on rates in Comparison Geographic Areas (86 FR 36384). Under our proposal, we would create two strata with the cutpoint set at 50 percent of attributed beneficiary years being for attributed beneficiaries who were dual-eligible or received the LIS. As such, there would be one stratum for ETC Participants whose aggregation groups had 50 percent or more of their attributed beneficiary years during the MY for beneficiaries who were dual-eligible or received the LIS, based on rates in Comparison Geographic Areas for aggregation groups with 50 percent or more attributed beneficiary years during the Benchmark Year being for dual-eligible or LIS beneficiaries. There would be a second stratum for ETC Participants whose aggregation groups had less than 50 percent of their attributed beneficiary years during the MY for beneficiaries who were dual-eligible or received the LIS, based on rates in Comparison Geographic Areas for aggregation groups with less than 50 percent attributed beneficiary years during the Benchmark Year being for dual-eligible or LIS beneficiaries. We proposed to determine whether an attributed beneficiary was dual-eligible or received the LIS for a given month using Medicare administrative data. In the CY 2022 ESRD PPS proposed rule, we stated our belief that this proposal would address concerns that socioeconomic factors may impact a beneficiary's likelihood to receive alternative renal replacement modalities, lowering the transplant rate and home dialysis rates for ETC Participants who provide services to low income beneficiaries. We also stated our expectation that stratifying the achievement benchmarks as proposed would increase home dialysis rate and transplant rates for such ETC Participants.

In the CY 2022 ESRD PPS proposed rule, we considered using more than two strata, in order to increase the precision of the achievement benchmarks and the degree of similarity between ETC Participants within a given stratum. However, we noted that increasing the number of strata would decrease the number of observations within each stratum, in turn decreasing statistical reliability. Additionally, analysis of the distribution of the home dialysis rate and transplant rate demonstrates that the underlying distribution does not lend itself to more than two strata, as the distribution is not multi-modal. For this reason, we proposed only two strata.

We sought public comment on our proposal to amend § 512.370(b) to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual-eligible or received the LIS, and on our proposal to create two strata for this purpose.

The following is a summary of the comments received on our proposal to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual eligible or received the LIS beginning for MY3, including our policy to create two strata for this purpose, and our responses.

Comment: Two commenters expressed support for addressing socioeconomic factors that impact ETC Participant achievement. These commenters also specifically supported CMS's recognition of the two proposed categories of beneficiaries who are economically disadvantaged for this purpose, namely beneficiaries who are dual-eligible or are LIS recipients. Several commenters stated that they agree that beneficiaries who are dual eligible or LIS recipients may be less likely to dialyze at home or receive a kidney transplant.

Response: We appreciate the commenters' support.

Comment: Multiple commenters stated that they supported stratifying the achievement benchmarks based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries were dual-eligible or LIS recipients. Several of these commenters expressed specific reasons for their support. A few of these commenters expressed support for stratification because they agree that stratification will support the goal of not disadvantaging ETC Participants who treat a high proportion of socioeconomically disadvantaged beneficiaries. One of these commenters

stated that stratification addresses concerns that socioeconomic factors outside the ETC Participant's control may impact a beneficiary's likelihood to receive alternative renal replacement modalities.

Response: We appreciate the commenters' support.

Comment: One commenter indicated that while dually eligible and LIS-recipient beneficiaries are important groups of underserved beneficiaries, this proxy does not illuminate the diversity of underserved communities or individuals facing health disparities due to complex socioeconomic circumstances in the United States.

Response: We understand that beneficiaries face challenges and barriers to choosing alternatives to traditional in-center dialysis in particular, and to accessing healthcare generally, related to their socioeconomic circumstances. We have recognized that there is variation in rates of home dialysis and transplantation by socioeconomic status. As discussed in the CY 2022 ESRD PPS proposed rule and in this section of this final rule, we know that socioeconomic status impacts the likelihood of a beneficiary receiving home dialysis or a transplant. In order to address these socioeconomic factors that impact ETC Participant Achievement, one of our proposals is to stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the LIS during the MY, in recognition that beneficiaries with lower socioeconomic status have lower rates of home dialysis and transplant than those with higher socioeconomic status.

Comment: One commenter asked that, if the Innovation Center intends to proceed with the proposal to stratify achievement benchmarks by the proportion of beneficiaries who are dual eligible or received the LIS, CMS should release information to the public regarding LIS beneficiaries so that the commenter could adequately analyze the ETC Model, and implement work plans to address the needs of this population.

Response: We generally do not share beneficiary-identifiable data related to a model tested under section 1115A of the Act with individuals or entities who are not participants in said model. However, CMS data for research is available via the Research Data Assistance Center (ResDAC). Additional information about ResDAC is available at resdac.org. A variety of aggregate data is also available directly from CMS at *data.cms.gov*, including the Mapping Medicare Disparities Tool.

Comment: One commenter supported any and all measures that incentivize care for beneficiaries who are dual-eligible or LIS recipients. However, this commenter expressed that the proposal to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual eligible or received the LIS might make dual-eligible and LIS recipients feel pressured to try a method of care that will not be successful for them. This commenter stated that these patients are often not used to advocating for themselves, so an incentive to the providers may seem like a threat to the patients.

Response: We believe that addressing disparities experienced by beneficiaries who are dual-eligible or LIS recipients by stratifying the achievement benchmarks, as proposed, will encourage ETC participants to decrease disparities in renal replacement modality choice across beneficiaries of different socioeconomic status. However, we are sensitive to concerns about ETC Participants exerting undue influence on this beneficiary population, in particular. As stated in the Specialty Care Models final rule, ETC Participants are prohibited from interfering with a beneficiary's freedom of choice or access to services under 42 CFR 512.120, and CMS will monitor for ETC Participant compliance with this requirement, including beneficiary complaints and appeals (85 FR 61341 through 61343).

Comment: A few commenters expressed concern about the proposal to stratify benchmarks by the proportion of attributed beneficiaries who are dual-eligible or LIS recipients. These commenters stated that they believed this approach could unnecessarily set a lower bar for achieving access to transplant and home dialysis by conflating differences owing to social risk factors and true differences in quality of care. Two of these commenters stated that they do not believe patient income or dual eligible status should be a factor in access to home dialysis or transplant and remain concerned that benchmark stratification could possibly worsen inequities by reducing Model-specific incentives to increase access to home dialysis for all patients.

Response: As discussed in the CY 2020 ESRD PPS proposed rule and in section V.B.6.c this final rule, we believe that stratifying achievement benchmarks based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries were dually-eligible for Medicare and Medicaid or received the LIS, based on rates in Comparison Geographic Areas, will address concerns that socioeconomic factors may impact a beneficiary's likelihood to receive alternative renal replacement modalities, lowering the transplant rate and home dialysis rates for ETC Participants who provide services to low income beneficiaries.

We do not believe that stratifying benchmarks by dual eligible and LIS recipients would unnecessarily set a lower bar for achieving access to transplant and home dialysis for these individuals. Rather, as discussed in the CY 2020 ESRD PPS proposed rule and in section V.B.6.c of this final rule, we expect that stratifying the achievement benchmarks as proposed will increase home dialysis rate and transplant rates for those ETC Participants who provide services to low-income beneficiaries. Specifically, rather than giving ETC Participants permission to provide lower levels of care to beneficiaries, we believe this approach will enable ETC Participants to address disparities in renal replacement modality choice among beneficiaries who are dual-eligible or LIS recipients by not disadvantaging them by comparing them to a standard set including a substantively different beneficiary population. While we understand that stratification would not provide a direct financial incentive for ETC Participants to focus on reducing disparities by improving the home dialysis rate and transplant rate for beneficiaries who are dual-eligible or receive the LIS, as ETC Participants who provide services to socioeconomically disadvantaged beneficiaries are likely to have lower home dialysis rates and transplant rates, stratification makes it more likely they will achieve a positive PPA that they can invest in caring for these beneficiaries. We believe ETC Participants will be able to use additional funds received as a result of receiving a positive PPA to improve their performance dialysis rates and transplant rates for all beneficiaries, including beneficiaries who are dual eligible and recipients of LIS.

Comment: Several commenters indicated that they supported stratifying achievement benchmarks based on dual eligible and LIS recipient status, but suggested modifications to the proposed approach. Some of these commenters suggested using a different cutpoint. Of the commenters suggesting a different cutpoint, some suggested a higher cutpoint and others suggested a lower cutpoint than 50 percent of attributed beneficiary years being for attributed

beneficiaries who were dual eligible or received the LIS. One commenter suggesting a higher cutpoint stated that this approach would better enable ETC Participants serving the highest percentage of low-income patients to successfully perform in the ETC Model. Some commenters suggesting modifications had suggested using more than two strata—including suggestions of three to ten strata—or using a sliding scale. Some commenters suggesting using more than two strata stated that doing so would provide more nuance to the PPA calculation. Generally, commenters suggesting alternative cutpoints or more than two strata stated that their suggested cutpoint or number of strata was more reflective of the commenters' own analysis of available data.

Response: We appreciate the commenters support for stratifying achievement benchmarks. As discussed in the proposed rule and previously in this section of the final rule, we considered using more than two strata in order to increase the precision of the achievement benchmarks and the degree of similarity between ETC Participants within a given stratum. This would have required the use of additional cutpoints—both lower and higher than 50 percent. In response to suggestions that we use more than two strata, as described in the CY 2022 ESRD PPS proposed rule and previously in this section of this final rule, increasing the number of strata would decrease the number of observations within each stratum, in turn decreasing statistical reliability. We continue to believe that that using more than two strata would decrease statistical reliability. Additionally, as described in the CY 2022 ESRD PPS proposed rule and in this section of this final rule, our analysis of the distribution of the home dialysis rate and transplant rate demonstrated that the underlying distribution does not lend itself to more than two strata, as the distribution is not multi-modal. In response to suggestions that we use a different cutpoint between strata, we believe that 50 percent is an appropriate cutpoint based on our analysis of the data. Based on the statistical properties of the underlying distribution, the 50 percent cutpoint is statistically appropriate, stable over time, and easily comprehendible to ETC Participants.

Comment: One commenter stated that while they support stratification, CMS should adjust performance within each stratum to account for variation within the stratum.

Response: While we recognize that there will be variation within each stratum, the commenter did not articulate what adjusting performance within each stratum should entail. Therefore, we are unable to respond with specificity to the suggestion that we adjust performance within each stratum. We continue to believe that stratification addresses variation in rates of home dialysis and transplantation for beneficiaries who are dual eligible or LIS recipients, but remain open to specific feedback regarding further adjustments for potential inclusion in future rulemaking.

Comment: Several commenters expressed support for CMS' proposal to use dual eligible and LIS recipient as proxies for socioeconomic status. One of these commenters stated that they agree that these are useful metrics to identify patients who may face clinical and non-clinical challenges to electing home dialysis or receiving a transplant.

Response: We thank commenters for their support.

Comment: A few commenters stated that they agreed with the intent behind, or the need for, an approach to address how socioeconomic factors impact beneficiaries' likelihood of receiving home dialysis or a kidney transplant and how that relationship impacts ETC Participants' performance, but stated that there may be better ways to account for this than stratification of the achievement benchmark. A few of these commenters suggested that CMS incorporate risk adjustment into the achievement benchmarking methodology, either instead of or in addition to stratification. Commenters suggesting risk adjustment stated that risk adjustment is more precise, because it is applied at the beneficiary-level, rather than the aggregate level. However, one such commenter acknowledged that, while they recommend risk adjustment, stratification may also address the same underlying issues.

Response: We considered other approaches for accounting for how the socioeconomic status of an ETC Participant's attributed beneficiaries may impact an ETC Participant's performance. However, we did not contemplate using risk adjustment for this purpose. While we appreciate that risk adjustment accounts for factors at an individual beneficiary level, adopting this policy would represent a significant departure from our proposal and would present its own challenges. For instance, without sufficient protections, the use of risk adjustment can result in payment inaccuracies due to factors such as upcoding. In addition, depending on the factors being used for risk-adjustment, there may be limitations in the available data, as discussed below. After considering the comments, we continue to believe that stratification of achievement benchmarks based on dual eligible and LIS recipient status is an appropriate approach for considering socioeconomic status under the ETC Model.

Comment: A few commenters recommended that CMS also consider incorporating additional social risk factors into the achievement benchmarking methodology. One such commenter acknowledged that current data on social determinants of health necessary to develop such a methodology is limited, citing Z-code data in particular, and that in the interim, stratification may address many of the concerns related to differential rates of home dialysis and transplantation between beneficiaries of higher and lower socioeconomic status. Another commenter stated that while dual eligibility and LIS recipient status can serve as proxies for social risk factors, this is not equivalent to patient-level data on individual risk factors. This commenter also pointed out that criteria for dual eligibility vary between states, and that being a LIS recipient is dependent on the beneficiary having been enrolled in a Part D plan.

Response: As stated in the CY 2022 ESRD PPS proposed rule and this section of this final rule, we continue to acknowledge that non-clinical factors, such as socioeconomic status, may impact a beneficiary's likelihood to receive home dialysis or a transplant. However, revising the proposed policy to include additional risk adjustments in the home dialysis rate based on socioeconomic status, as suggested by some of the commenters, would be a significant departure from the policy originally proposed. We also agree with the commenter who acknowledged the current limitations in data on individual-level social determinants of health. At this time, we continue to believe stratification using the proportion of attributed beneficiaries who are dual-eligible or LIS recipients is an appropriate means of considering socioeconomic status under the ETC Model. Moreover, while we acknowledge that dual eligibility and LIS recipient status may not capture socioeconomic status in the same way for all beneficiaries—due to variation between states or the necessity of being enrolled in a Part D plan to be an LIS recipient—as stated in the CY 2022 ESRD PPS proposed rule and in section V.B.5.b of this final rule, dual eligibility and LIS recipient status are correlated with lower rates of home dialysis and transplantation. As such, ETC

Participants who have a higher proportion of attributed beneficiaries who are dual eligible or LIS recipients may be less likely to achieve high home dialysis and transplant rates than ETC Participants who have a lower proportion of attributed beneficiaries who are dual-eligible or LIS recipients. Therefore, we believe dual eligible and LIS status are appropriate proxies for socioeconomic status. If Z-codes become more widely used and more such codes become available for use into the claims process, such that Z-code data becomes appropriate for use, we may consider incorporating such data into the ETC Model methodology through future rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.370(b)(2) to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual eligible or received the LIS beginning for MY3, and to create two strata for this purpose, without modification.

6. PPA Improvement Benchmarking and Scoring

a. Background on Improvement Benchmarking and Scoring

Another part of the scoring methodology for the PPA is improvement scoring. We calculate an ETC Participant's improvement score under § 512.370(c) by comparing MY performance on the home dialysis rate and transplant rate against past ETC Participant performance. As described in the Specialty Care Models final rule, the purpose of the improvement score is to acknowledge efforts made in practice transformation to improve rates of home dialysis and transplants (85 FR 61318). The percentage improvement in the ETC Participant's MY performance on the home dialysis rate and the transplant rate relative to the Benchmark Year rate is scored as follows:

- Greater than 10 percent improvement relative to the Benchmark Year rate: 1.5 points
- Greater than 5 percent improvement relative to the Benchmark Year rate: 1 point
- Greater than 0 percent improvement relative to the Benchmark Year rate: 0.5 points
- Less than or equal to the Benchmark Year rate: 0 points

However, when the Benchmark Year rate is zero, an improvement score for the MY cannot be calculated. This is because, when calculating percent change, as used in improvement scoring, the Benchmark Year rate is the denominator. As such, we cannot calculate percent improvement for an aggregation group with a rate of zero during the Benchmark Year because the denominator of the improvement score calculation is zero, and division by zero is undefined. Thus, an aggregation group in this situation will not receive an improvement score if the Benchmark Year rate is zero, even if the aggregation group has made improvements in the home dialysis rate and/or the transplant rate between the Benchmark Year and MY.

b. Incentivizing Improvement for Socioeconomically Disadvantaged Beneficiaries

As described in the CY 2022 ESRD PPS proposed rule and in section V.B.5.b of this final rule, beneficiaries who are dual-eligible or receive the LIS are less likely than beneficiaries who are not dual-eligible and do not receive the LIS to dialyze at home or receive a kidney transplant. As described in the CY 2022 ESRD PPS proposed rule and previously in this section of the final rule, we proposed to stratify achievement benchmarks by the proportion of attributed beneficiary years for beneficiaries who are dual-eligible or LIS recipients to avoid disadvantaging ETC Participants who provide care for a high proportion of these beneficiaries. However, we noted that the proposed stratification would not provide a direct financial incentive for ETC Participants to focus on reducing disparities by improving the home dialysis rate and transplant rate for beneficiaries who are dual-eligible or receive the LIS. In the CY 2022 ESRD PPS proposed rule, we stated our interest in creating that incentive as part of the ETC Model, as these beneficiaries may require additional support from ETC Participants to pursue home dialysis and transplant as alternative renal replacement modalities (86 FR 36384).

c. Changes to Improvement Benchmarking and Scoring

(1) Revised Improvement Calculation

As described previously, when the Benchmark Year rate for an aggregation group is zero, the aggregation group cannot receive an improvement score, even if the aggregation group has made improvements in the home dialysis rate and transplant rate between the Benchmark Year and MY. To address this issue, we proposed to amend § 512.370(c)(1) to change the improvement calculation such that the aggregation group's Benchmark Year rate cannot be zero. Specifically, for MY3 through MY10, we proposed to add one beneficiary month to the numerator of the home dialysis rate and the transplant rate for the Benchmark Year rate for an ETC Participant's aggregation group Benchmark Year when that rate is zero (86 FR 36384). CMS did not propose to change the denominator of the Benchmark Year rate calculations because doing so would negate the purpose of mathematically correcting ETC Participants' improvement scoring. In the CY 2022 ESRD PPS proposed rule, we stated that CMS does not expect that adding a beneficiary month to the numerator of the Benchmark Year rate calculations, as proposed, would affect the improvement scoring enough to change the number of points awarded to the ETC Participant, and has the advantage that it would enable an improvement score to be calculated, even when the Benchmark Year rate is zero.

The following is a summary of the comments received on our proposal to modify the calculation of the an ETC Participant's Benchmark Year home dialysis rate and transplant rate to prevent it from being zero, such that an improvement score can be calculated, and our responses.

Comment: A few commenters stated that they support the proposal to add one beneficiary month to the numerator of the home dialysis rate and the transplant rate for the Benchmark Year rate for an ETC Participant's aggregation group Benchmark Year when that rate is zero.

Response: We appreciate commenters' support for this proposal.

Comment: One commenter suggested that CMS change the improvement scoring methodology to allow ETC Participants to attain the top tier of scoring—2 points—through improvement alone.

Response: As stated in the Specialty Care Models final rule (85 FR 61322), while we acknowledge the importance of incentivizing improvement over time, we do not award full points for improvement for consistency with other CMS programs and initiatives employing similar improvement scoring methodologies. Additionally, with the introduction of the Health Equity Incentive, as described in the CY 2022 ESRD PPS proposed rule and in section V.B.6.c.(2) of this final rule, ETC Participants are able to, beginning for MY3, attain the full 2 points for improvement if they demonstrate greater than 10 percent improvement relative to the Benchmark Year rate and earn the Health Equity Incentive.

Final Rule Action: After considering public comments, we are finalizing our

proposal in our regulation at § 512.370(c)(1) to add one beneficiary month to the numerator of the ETC Participant's Aggregation Group's home dialysis rate and transplant rate for the Benchmark Year when calculating the ETC Participant's improvement score beginning for MY3, without modification.

(2) Health Equity Incentive

To incentivize ETC Participants to decrease disparities in the home dialysis rate and transplant rate between beneficiaries who are dual-eligible or LIS recipients and those who are not, we proposed to add a Health Equity Incentive to the improvement scoring methodology (86 FR 36385). We proposed to define the Health Equity Incentive at § 512.310 as the amount added to the ETC Participant's improvement score calculated as described in § 512.370(c)(1) if the ETC Participant's aggregation group demonstrated sufficient improvement on the home dialysis rate or transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients between the Benchmark Year and the MY. We proposed that this improvement on the home dialysis rate or transplant rate would be based on the performance of the ETC Participant's aggregation group.

As noted in the CY 2022 ESRD PPS proposed rule and previously in this section of the final rule, socioeconomic factors impact a beneficiary's receipt of alternative renal replacement modalities. Beneficiaries with limited resources may require more assistance from ESRD facilities and Managing Clinicians to use alternative renal replacement modalities. In the CY 2022 ESRD PPS proposed rule, we stated our belief that our proposal to add a Health Equity Incentive would benefit these beneficiaries and improve scoring for home dialysis rate and transplant rate for ETC Participants that serve disproportionately high numbers of beneficiaries with lower socioeconomic status. To earn the Health Equity Incentive, ETC Participants would have to demonstrate sufficiently significant improvement on the home dialysis rate or transplant rate among their attributed beneficiaries who are dual eligible or receive the LIS between the Benchmark Year and the MY. ETC Participants who earn the Health Equity Incentive would receive a 0.5-point increase on their improvement score, thus increasing the maximum improvement score to 2 points. In the CY 2022 ESRD PPS proposed rule, we stated our belief that the proposed Health Equity Incentive would benefit attributed beneficiaries who are dual eligible or receive the LIS, by encouraging ETC Participants to address disparities in access to alternative renal replacement modalities among these beneficiaries. We also stated our belief that providing this incentive for ETC Participants to increase their home dialysis and transplant rate among their dual eligible or LIS beneficiary population would ultimately reduce this disparity in access for the beneficiaries in question. Therefore, we stated our belief that this incentive to reduce socioeconomic disparities in access to alternative renal replacement modalities would be an improvement to the PPA scoring methodology.

We proposed to amend § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology, beginning for MY3. We proposed that the Health Equity Incentive would be equal to 0.5 points, which would be added to the ETC Participant's improvement score for the home dialysis rate or for the transplant rate, calculated as described in § 512.370(c)(1), such that the maximum improvement score would increase from 1.5 points to 2 points for ETC Participants that earn the Health Equity Incentive. Therefore, for those ETC Participants that earn the Home Equity Incentive, we proposed that the ETC Participant's improvement score for the home dialysis rate and for the transplant rate would be the sum of the improvement score calculated as described in § 512.370(c)(1) and the Health Equity Incentive. We noted in the CY 2022 ESRD PPS proposed rule that the Health Equity Incentive would allow ETC Participants to increase their improvement score, and thereby increase their payment adjustment.

We proposed to award the Health Equity Incentive to an ETC Participant if the ETC Participant's aggregation group's home dialysis rate and/or transplant rate among attributed beneficiaries who are dual-eligible or LIS recipients increases by 5 or more percentage points from the Benchmark Year to the MY. We stated our belief in the CY 2022 ESRD PPS proposed rule that 5-percentage points is the correct threshold for awarding the Health Equity Incentive based on our analysis of Medicare claims. Five percentage points is one standard deviation above the average difference between the home dialysis rate and the transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients and those beneficiaries who are not dual-eligible or LIS recipients, rounded to the nearest integer. In the CY 2022 ESRD PPS proposed rule, we noted that we anticipate improvement in home dialysis and transplant rates among dual-eligible or LIS recipients between the MY and the Benchmark Year, but that we expect that attaining the proposed threshold for earning the Health Equity Incentive would generally require significant effort on the part of the ETC Participant.

We proposed that an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to be dual-eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dually eligible for Medicare and Medicaid or a LIS recipient. We proposed to determine whether an attributed beneficiary was dual-eligible or received the LIS using Medicare administrative data.

We proposed to modify § 512.370(c) such that the improvement benchmarking and scoring methodology for MY1 and MY2 would be specified at § 512.370(c)(1), and the improvement benchmarking and scoring methodology for MY3 through MY10, described earlier, would be specified at § 512.370(c)(2). We sought comment on the proposal to modify § 512.370(c) accordingly.

In the CY 2022 ESRD PPS proposed rule, we considered using a rolling approach to setting the threshold for earning the Health Equity Incentive, such that the threshold would be recalculated every other MY, to reflect changes in underlying disparities. Under this approach, we would calculate the threshold as one standard deviation above the average difference between the home dialysis rate and the transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients and those beneficiaries who are not dual-eligible or LIS recipients, rounded to the nearest integer. We would calculate this threshold either using data from the Benchmark Year, such that ETC Participants would know the threshold for earning the Health Equity Incentive in advance of the MY, or using data from the MY, such that the threshold for earning the Health Equity Incentive would accurately reflect the magnitude of the disparity observed during the MY. However, we stated our belief that setting a threshold for earning the Health Equity Incentive applicable for all MYs, beginning for MY3, would be more appropriate. We noted that this approach would be in keeping with the intent of the proposed Health Equity Incentive, which is to provide ETC Participants a financial incentive to focus on decreasing the disparity in the home dialysis and transplant rates between beneficiaries who are dual-eligible or LIS recipients, and those who

are not. We further stated our belief that providing ETC Participants clear information about what they need to achieve to earn the Health Equity Incentive in advance would best enable them to work towards the goal.

We proposed that ETC Participants in aggregation groups that fall below a low-volume threshold would be ineligible to earn the Health Equity Incentive (86 FR 36386). Specifically, we proposed that an ETC Participant in an aggregation group with fewer than 11 attributed beneficiary years comprised of months in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries are dual eligible or LIS recipients during either the Benchmark Year or the MY would be ineligible to earn the Health Equity Incentive. We selected this particular low-volume threshold for consistency with the low-volume threshold for the applicability of the PPA generally, as specified at § 512.385. We stated our belief that it is necessary to apply a low volume threshold in determining whether an ETC Participant has earned the Home Equity Incentive to ensure statistical reliability of the home dialysis rate and transplant rate calculations. This statistical reliability provides consistency in the home dialysis rate and transplant rate calculations. Therefore, similar results are produced under consistent conditions when applying a low volume threshold to ETC Participants. We proposed a low-volume threshold specific to attributed beneficiaries who are dual-eligible or receive the LIS because whether an ETC Participant has earned the Health Equity Incentive is being assessed on this subset of attributed beneficiaries.

We proposed to amend the Modality Performance Score (MPS) methodology to incorporate the Health Equity Incentive. To that end, we proposed to modify § 512.370(d) such that the calculation of the MPS for MY1 and MY2 is specified at § 512.370(d)(1), and the calculation of the MPS for MY3 through MY10 is specified at § 512.370(d)(2). We proposed that the formula for the MPS for MY3 through MY10 would be the following:

Modality Performance Score
= 2 × (*Higher of the home dialysis achievement or* (*home dialysis improvement score* + *Health Equity Bonus* †))
+ (*Higher of the transplant achievement or* (*transplant improvement score* + *Health Equity Bonus* †))

† The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant and provided that the ETC Participant is not ineligible to receive the Home Equity Incentive as described in proposed § 512.370(c)(2)(iii).

We sought comment on our proposed definition for the Health Equity Incentive at § 512.310 and our proposal to amend § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology for the home dialysis rate and the transplant rate. We also sought comment on our proposal to set the threshold for earning the Health Equity Incentive at 5-percentage points improvement from the Benchmark Year to the MY.

The following is a summary of the comments received on the proposal to introduce the Health Equity Incentive to the improvement scoring methodology beginning for MY3, and our responses.

Comment: Many commenters expressed support for the concept of addressing socioeconomic disparities in access to alternative renal replacement modalities through the ETC Model. A few commenters highlighted that particular groups that tend to experience healthcare disparities—including patients of lower socioeconomic status and patients from racial and ethnic minorities—make up a significant portion of dialysis patients.

Response: We appreciate the commenters' support.

Comment: One commenter stated that the racial and ethnic disparities in access to home dialysis care have long existed, but that the COVID–19 pandemic has exacerbated them. According to the commenter, increased access to home dialysis modalities would give those historically disadvantaged patients the chance to avoid potentially dangerous contact with COVID–19 infected individuals by reducing visits to a dialysis clinic or doctor's office. The commenter stated that, for all of these important reasons, they strongly support CMS's efforts to advance home dialysis through the ETC Model.

Response: We agree with the commenter that COVID–19 pandemic has highlighted one of the benefits of home dialysis—that dialyzing at home reduces the risk that an individual patient is exposed to COVID–19 or other communicable diseases in the course of their dialysis care—and we agree that beneficiaries should have equal access to this modality for this and other reasons.

Comment: A few commenters expressed concerns about the impact of the ETC Model on health disparities. One commenter expressed concern about certain design aspects of the ETC Model that could have unintended effects that perpetuate existing kidney health disparities. Another commenter stated that CMS is not providing additional resources to ETC Participants to give extra assistance to disadvantaged patients.

Response: We believe that the ETC Model will improve access to alternative renal replacement modalities, including home dialysis and transplantation, for all types of beneficiaries. We further believe the Model will not cause any unintended effects that perpetuate existing kidney health disparities. Indeed, with the introduction of achievement benchmark stratification and the Health Equity Incentive, as described in the CY 2022 ESRD PPS proposed rule and sections V.B.5.c.(2) and V.B.6.c.(2) of this final rule, respectively, we are testing ways to directly address socioeconomic disparities in access to alternative renal replacement modalities. We believe the proposed Health Equity Incentive, in particular, will benefit attributed beneficiaries who are dual eligible or receive the LIS, by encouraging ETC Participants to address disparities in access to alternative renal replacement modalities among these beneficiaries.

Comment: The majority of commenters generally supported the Health Equity Incentive. Most of these commenters supported the Health Equity Incentive proposal without providing any additional recommendations.

Response: We appreciate commenters' support.

Comment: Several commenters stated that they supported creating a Health Equity Incentive, but indicated that it is important that the thresholds for earning the Health Equity Incentive are achievable for ETC Participants.

Response: We agree that it is important for the thresholds for earning the Health Equity Incentive to be achievable for ETC Participants. We believe that this is the case. First, by establishing the thresholds for all MYs, starting for MY3, through this rulemaking, ETC Participants will have clear information in advance about what they need to achieve to earn the Health Equity Incentive to enable them to work towards the goal of increasing access to home dialysis and transplant for beneficiaries who are dual eligible and LIS recipients for the remaining duration of the ETC Model test. Second, as described in greater detail below, we are modifying our proposal such that we would award the Health Equity Incentive to an ETC Participant if the ETC Participant's aggregation group's home dialysis rate and/or transplant rate among attributed beneficiaries who are dual eligible or LIS recipients increases

by at least 2.5 percentage points from the Benchmark Year to the MY, which we believe will be a more attainable threshold for ETC Participants than the proposed threshold of 5 percentage points.

Comment: Several commenters expressed specific support for our proposal that the Health Equity Incentive would be worth 0.5 improvement points.

Response: We appreciate the commenters support.

Comment: Several commenters stated that they supported the introduction of the Health Equity Incentive, but recommended that we set a lower threshold for ETC Participants to earn the Health Equity Incentive. These commenters stated that they believed that a five-percentage point increase to earn the Health Equity Incentive is too high, and may not be attainable for ETC Participants. A few of these commenters stated that setting the threshold too high would be discouraging—that ETC Participants would not try to increase home dialysis rates and transplant rats among their beneficiaries who are dual eligible or LIS recipients because they would not believe attaining a five-percentage point increase would be possible. One commenter stated that a lower threshold would mean that more ETC Participants would earn the incentive, which would result in higher payments and therefore more resources for those participants to support disadvantaged beneficiaries choosing alternative renal replacement modalities. One commenter stated that a 5-percentage point increase from year to year is likely an unachievable goal based on historic data. Several commenters suggested alternative methods for awarding the Health Equity Incentive. A few of these commenters suggested a lower percentage point threshold, such as 1.25-percentage points. Others suggested alternative methodologies, such as a percentage or percentage point increase over the Benchmark Year rate, or a percent increase instead of a percentage point increase.

Response: We appreciate commenters' suggestions of alternative methods for awarding the Health Equity Incentive. We agree with commenters' concerns that setting the threshold for awarding the Health Equity Incentive too high could undermine the intent of the policy. As stated in the CY 2022 ESRD PPS proposed rule (86 FR 36385) and in this section of this final rule, 5 percentage points is equal to one standard deviation above the average difference between the home dialysis rate and the transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients and those beneficiaries who are not dual-eligible or LIS recipients, rounded to the nearest integer. We also stated our expectation that attaining the proposed threshold for earning the Health Equity Incentive would generally require significant effort on the part of the ETC Participant. However, we are persuaded by the specific evidence provided by commenters that our proposed threshold was likely unachievable based on historic data. As such, we agree with commenters that we should lower the threshold for awarding the Health Equity Incentive.

After considering the alternatives suggested by commenters, we continue to believe that a percentage-point increase is appropriate for awarding the Health Equity Incentive. However, rather than a 5-percentage point increase, we believe that at 2.5-percentage point increase is more appropriate. Specifically, we believe that a 2.5 percentage point threshold presents a more achievable goal than the 5-percentage point increase described in the proposed rule. However, as compared to the 1.25 percentage point increase suggested by the commenters, we believe using a 2.5 percentage point increase as the threshold for earning the Health Equity Incentive will incentivize ETC Participants to make substantial reductions in disparities between their Beneficiaries who are dual eligible or LIS recipients and those who are not over the course of the ETC Model.

Comment: One commenter stated that the Health Equity Incentive should be considered for other value-based care models.

Response: If we adopt the Health Equity Incentive for one or more other models, we would do so by amending that model's governing documentation, which may involve notice and comment rulemaking.

Comment: A few commenters encouraged CMS to explore and consider adding additional characteristics or social drivers of health disparities in addition to dual eligibility and LIS status as part of the Health Equity Incentive calculation under the ETC Model. A few of these commenters suggested that we do so now, and one of these commenters suggested that we do so pending further study and analysis. One commenter suggested that we include race as part of the Health Equity Incentive calculation.

Response: We appreciate the suggestion that we consider including other factors in the Health Equity Incentive calculation under the ETC Model. However, we agree with the commenter who suggested that we consider adding additional characteristics or social drivers of health disparities only after further study and analysis. Thus, while we are only awarding the Health Equity Incentive on the basis of improvement among beneficiaries who are dual eligible or LIS recipients at this time, we may consider additional factors for the future after we complete research and analysis on those factors. Any additional factors would be incorporated through subsequent rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology, with one modification. Specifically, we are modifying our regulation at §§ 512.370(c)(2)(i) and (c)(2)(ii) to change the threshold for earning the Health Equity Incentive from a 5-percentage point increase to a 2.5-percentage point increase in the ETC Participant's home dialysis rate and transplant rate, respectively, among attributed beneficiaries who are dual-eligible or LIS recipients from the Benchmark Year to the MY. We are also finalizing our proposed definition of Health Equity Incentive at § 512.310 without modification.

7. PPA Reports and Data Sharing

a. Background on Beneficiary Attribution and Performance Reporting

Under the ETC Model, as described in 42 CFR 512.360, CMS attributes ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries to an ETC Participant for each month during a MY based on the beneficiary's receipt of services during that month. CMS performs this attribution for a MY retrospectively, after the end of the MY. As described in § 512.365, each ETC Participant's performance is assessed based on the transplant rate and home dialysis rate among the population of beneficiaries attributed to the ETC Participant. As described in 42 CFR 512.370 and 42 CFR 512.380, these rates are used to calculate the ETC Participant's MPS and, in turn, the ETC Participant's PPA. The PPA is then used to adjust certain Medicare payments of the ETC Participant during 6-month PPA periods, with the first PPA Period taking place from July 1, 2022, through December 31, 2022. As described in 42 CFR 512.390(a), CMS will notify each ETC Participant, in a form and manner determined by CMS, of the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period no later

than one month before the start of the applicable PPA Period.

In order to ensure ETC Participants have timely access to these ETC Model reports, in the CY 2022 ESRD PPS proposed rule (86 FR 36386 through 36391), we proposed to add a new paragraph (b) to § 512.390 to establish a process for CMS to share certain beneficiary-identifiable and aggregate data with ETC Participants pertaining to their participation in the ETC Model. As we stated in the CY 2022 ESRD PPS proposed rule, CMS believes that ETC Participants need this data to successfully coordinate the care of their ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries; to succeed under the ETC Model; and to assess CMS's calculations of the individual ETC Participant's PPA for a given PPA Period. Specifically, we stated CMS believes that ETC Participants must have a clear understanding of the beneficiaries CMS has attributed to them under the ETC Model and how each attributed beneficiary has factored into the ETC Participant's home dialysis rate, transplant waitlist rate, and living donor transplant rate, to better identify care coordination and care management opportunities, and to have the opportunity to seek targeted review of CMS's calculation of the MPS. We noted that the purpose of the targeted review process, established under current § 512.390(b), which we would redesignate as paragraph (c), is to determine whether an incorrect PPA has been applied during the PPA Period. We stated that CMS additionally believes that timely access to this data is important and proposed to require CMS to make this data available twice a year, prior to each PPA Period in an MY.

In the following sections of this final rule, we describe the process that we proposed for CMS to share and for ETC Participants to retrieve certain beneficiary-identifiable attribution data and performance data, as well as the protections that we proposed to apply to this data under a data sharing agreement with CMS. We also describe our proposed process for sharing certain aggregate, de-identified performance data with ETC Participants.

b. CMS Sharing of Beneficiary-Identifiable Data

We proposed to establish a process in new § 512.390(b)(1) under which CMS would share certain beneficiary-identifiable data with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model. We proposed that, in accordance with the timing of the notification requirement described in § 512.390(a), CMS would be required to make the beneficiary-identifiable data pertaining to a given PPA Period available for retrieval by ETC Participants no later than 1 month before the start of that PPA Period. The ETC Participant would be able to retrieve this data at any point during the relevant PPA Period, but, in accordance with current § 512.390(b)(1), which would be redesignated as paragraph (c)(1), the ETC Participant would have 90 days from the date that CMS shares the MPS, including the data CMS used in calculating the MPS, to request a targeted review. We proposed that CMS would notify ETC Participants of the availability of the beneficiary-identifiable data for a relevant PPA Period and the process for retrieving that data, through the ETC listserv and through the ETC Model website, available at *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model*.

Regarding the specific beneficiary-identifiable data that CMS would be required to share with ETC Participants, we proposed in § 512.390(b)(1)(ii)(A) to include, when available, the following data for each PPA Period: The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers (MBIs), dates of birth, dual-eligible status, and LIS recipient status. We stated in the CY 2022 ESRD PPS proposed rule that we believe that the patient's name, MBI, and date of birth constitute the minimum elements to enable an ETC Participant to properly identify an attributed beneficiary, and to confirm the identity of an attributed beneficiary during any communications with a beneficiary or a beneficiary's caregiver, as appropriate and allowable. In addition, we stated the ETC Participant needs to be aware of each attributed beneficiary's dual-eligible status and LIS recipient status to understand how each attributed beneficiary contributed to how CMS calculated the ETC Participant's Health Equity Incentive, if finalized. We proposed in § 512.390(b)(1)(ii)(B) that this beneficiary-identifiable data also would include, when available, data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable, the number of months the beneficiary was attributed to the ETC Participant, received home dialysis, self-dialysis, or nocturnal in-center dialysis, or was on a transplant waitlist; and the number of months that have passed since the beneficiary has received a living donor transplant, as applicable. We stated that we believe that sharing these data elements would help the ETC Participant understand and, as appropriate, seek targeted review of CMS's calculation of the ETC Participant's MPS, and otherwise understand how CMS adjusted the ETC Participant's Medicare payments by the PPA.

In the CY 2022 ESRD PPS proposed rule (86 FR 36387), we stated that we recognized there are sensitivities surrounding the disclosure of individually-identifiable (beneficiary-specific) health information, and we noted that a number of laws place constraints on the sharing of individually identifiable health information. We noted that, 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 for the disclosure. In this instance, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule permits this proposed disclosure of individually identifiable health information by us to ETC Participants if this proposed disclosure is required by law. We explained that under the HIPAA Privacy Rule, covered entities (defined as health care plans, health care providers that submit certain transactions electronically, and health care clearinghouses) are barred from using or disclosing protected health information (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. ETC 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.

As we discussed in the CY 2022 ESRD PPS proposed rule, the proposed disclosure of ETC Model beneficiary-identifiable data would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI as ''required by law.'' Under 45 CFR 164.512(a)(1), a covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.[275] We proposed to establish

[275] Under 45 CFR 164.103, ''Required by law'' means ''a mandate contained in law that compels

a requirement under § 512.390(b)(1) for CMS to share this data with ETC Participants.

In the CY 2022 ESRD PPS proposed rule, we further noted that 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 (name, Social Security number, 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 stated in the CY 2022 ESRD PPS proposed rule that we believe that the proposed data disclosures are consistent with the purposes for which the data discussed in this rule was collected, and thus, should 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''), system of records number 09–70–0571, and the Health Resources and Services Administration (''HRSA'') Organ Procurement and Transplantation Network (''OPTN'')/ Scientific Registry of Transplant Recipients (''SRTR'') Data System, system of records number 09–15–0055.

In the CY 2022 ESRD PPS proposed rule, we expressed that establishing a regulatory requirement for CMS to share the beneficiary-identifiable data described previously would be appropriate for the ETC Model for several reasons. First, we stated that we believe that all ETC Participants not only desire but need this data to know which beneficiaries CMS has attributed to them (and thus is holding them financially accountable for such beneficiaries' individual contributions to the ETC Participant's performance measures described in 42 CFR part 512, subpart C, with the proposed modifications described in this proposed rule, if finalized), and for each ETC Participant to understand the basis by which CMS computed their MPS. Second, we stated that CMS believes that all ETC Participants, regardless of size, would have the capability of managing and meaningfully using the shared data. We noted that we would provide the data in a form and manner that CMS believes is user-friendly. In addition, the ETC Participant would be able to review the beneficiary-identifiable data along with the aggregated data, which should help the ETC Participant understand the data CMS would share with the ETC Participant. Finally, we stated that CMS believes that any other approach to making beneficiary-identifiable data available, including the alternative proposal considered by CMS and described later in this section, would impose additional operational burdens on CMS and administrative burdens on both CMS and the ETC Participants without producing any meaningful privacy or security benefit.

In the CY 2022 ESRD PPS proposed rule, we noted that we considered an alternative proposal for making beneficiary-identifiable data available to ETC Participants based on the data sharing policies currently used in many models tested under section 1115A of the Act, which would involve ETC Participants formally requesting the data from CMS before CMS could share the data. In particular, ETC Participants would have the opportunity to request the ''minimum necessary'' PHI for their own ''health care operations'' as defined in 45 CFR 164.501 and CMS would be permitted to disclose the requested data based on the HIPAA Privacy Rule provisions that permit disclosures of PHI for the recipient's health care operations purposes as described in 45 CFR 164.506(c)(4). We stated that under this alternative approach, ETC Participants that request this information would have to attest to compliance with specific HIPAA requirements in addition to, or as part of, the data sharing agreement described in section V.B.7.b.c of the CY 2022 ESRD PPS proposed rule and the next section of this final rule.

In the CY 2022 ESRD PPS proposed rule, we stated that after considering this option, we believed that having the ETC Participant request the data from CMS would add steps in the process that would cause administrative burden for both CMS and ETC Participants, and operational cost and burden for CMS. We also stated that we further believed that adding these steps would not produce a meaningful privacy or security benefit based on the specific circumstances of this ETC Model. We noted that both this option and the proposed approach would require that the ETC Participant complete and sign a data sharing agreement, and both would allow an ETC Participant to decline receiving beneficiary-identifiable data by declining to complete or sign a data sharing agreement. As such, we stated that there would be no meaningful privacy or security benefits that this option would create that were not already realized by the proposed approach to data sharing in the ETC Model. We also anticipated that all ETC Participants would want and need, and overwhelmingly would request, the data described previously, would be capable of handling such data, and would take the steps necessary to obtain the data. In addition, we stated that under an alternative approach based on the HIPAA provisions for the ETC Participant's ''health care operations,'' CMS would only be able to disclose the beneficiary-identifiable data for a purpose listed in paragraph (1) or (2) of the definition of ''health care operations'' in 45 CFR 164.501. However, we noted that we also believe it is crucial that an ETC Participant has the opportunity to understand how CMS calculated the ETC Participant's PPA for a PPA Period, and have the information needed to request a targeted review of CMS's MPS calculation if the ETC Participant believes CMS made an error.

Given the policies we were proposing for data sharing, we also proposed to modify the title of § 512.390 from ''Notification and targeted review'' to ''Notification, data sharing, and targeted review.'' We proposed this change so that the section title would more accurately reflect the contents of the section.

We solicited public comment on our proposal to require, under proposed § 512.390(b)(1), that CMS make available certain beneficiary-identifiable attribution and performance data for retrieval by ETC Participants no later than one month prior to the start of each PPA Period, and on our considered alternative to this proposal.

The following is a summary of the comments received on our proposal to require that CMS make available certain beneficiary identifiable attribution and performance data for retrieval by ETC Participants no later than one month prior to the start of each PPA Period, and our responses.

an entity to make a use or disclosure of protected health information and that is enforceable in a court of law.'' It includes, among other things, ''statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.''

Comment: We received many comments in support of the need for data sharing under the ETC Model. One commenter asserted that it is essential for ETC Participants to have access to the data elements CMS described in the CY 2022 ESRD PPS proposed rule to allow ETC Participants to make informed decisions and implement changes to clinical processes that permit improvement over time. Another commenter stated that the availability of beneficiary-level data under the ETC Model would be helpful in caring for and providing appropriate care to ESRD Beneficiaries. Another commenter stated that the data CMS proposed to share would assist ETC Participants in establishing targeted interventions to increase rates of the contemplated dialysis modalities and transplant waitlisting, and that it would help ETC Participants decrease health disparities.

Response: We thank the commenters for their support.

Comment: One commenter expressed agreement with the expected uses of beneficiary-identifiable data by ETC Participants that CMS described in the CY 2022 ESRD PPS proposed rule, including requesting targeted review of the MPS calculation, care management or coordination, and quality improvement.

Response: We appreciate this comment. We continue to believe that requesting targeted review of the MPS calculation, care management or coordination, and quality improvement constitute appropriate uses of the beneficiary-identifiable data that CMS would share with ETC Participants, and we are pleased this commenter agrees with these expected uses.

Comment: We received some comments regarding the timing and frequency of data sharing under the ETC Model. Some commenters expressed support for our proposal to share data prior to each PPA Period. A few commenters proposed that CMS share data more frequently than proposed. A couple commenters proposed that CMS share the data described in the CY 2022 ESRD PPS proposed rule on a quarterly basis. Another commenter proposed that CMS share the data on as close to a real-time basis as possible, suggesting either a quarterly or a monthly basis. This commenter asserted that sharing data on a quarterly or monthly basis would help ensure that the data is not outdated, and that it could better help guide interventions by ETC Participants to increase home dialysis and transplant rates.

A couple commenters recommended that CMS share the data on a monthly basis. One such commenter maintained that, for an ETC Participant to meaningfully track its performance, the ETC Participant should have access to monthly reports detailing its attributed beneficiary population. The same commenter also suggested that they anticipate that sharing data on a monthly basis would impose minimal burden on CMS, that such data sharing frequency would allow CMS and ETC Participants to address potential errors through targeted reviews on a smaller scale and on a rolling basis, and that more timely access to data would better support ETC Participants in increasing transplant waitlisting and monitoring their performance.

Response: We thank the commenters for their feedback. While we agree, in general, that having access to more timely data would incur many benefits for CMS and ETC Participants alike, including the ones identified by commenters, we believe that the schedule we proposed for sharing data affords ETC Participants sufficient time to conduct the activities for which CMS proposed allowing the ETC Participant to use the data, namely: To assess CMS's calculations underlying the ETC Participant's MPS, and to conduct care management, care coordination, and quality improvement activities. In addition, we believe that sharing data biannually, no later than one month ahead of each PPA Period, gives ETC Participants sufficient opportunity to track or monitor their performance and otherwise increase transplant waitlisting. Further, as described in § 512.360 of our regulations, CMS conducts beneficiary attribution for each month of a MY retrospectively after the end of each MY. Accordingly, CMS would not necessarily have accurate beneficiary-identifiable data to share with the ETC Participant on a monthly or quarterly basis to the extent that a beneficiary's attribution status can change during a given MY. In other words, CMS is unable to share accurate, final beneficiary-identifiable data on the ETC Participant's attributed beneficiaries more often than biannually, after the end of the applicable MY.

In addition, because we conduct beneficiary attribution retrospectively, we disagree with the commenter's suggestion that sharing data monthly would impose minimal burden on CMS. Sharing data monthly or quarterly would in effect require CMS to conduct beneficiary attribution monthly or quarterly, even though CMS is basing its MPS calculations on beneficiary attribution run only biannually, which would impose more than minimal burden on CMS. We similarly disagree with the commenter's suggestion that sharing data more frequently would enable CMS and ETC Participants to address potential errors through targeted reviews on a smaller scale and on a rolling basis. CMS did not propose any changes to when CMS computes the MPS or applies it to determine the ETC Participant's PPA. Because CMS will still be applying the PPA according to the schedule provided in § 512.355, sharing data more frequently than proposed would not give CMS and ETC Participants the ability to address potential errors through targeted reviews on a smaller scale or on a rolling basis.

For the same reasons, we disagree with the commenter's concern that, under CMS's proposal to share beneficiary-identifiable data prior to each PPA Period, the data shared would be outdated. Under § 512.365, CMS calculates the ETC Participant's MPS based on the ETC Participant's performance during a given MY. Any beneficiary-identifiable data shared during an MY would not necessarily be accurate because a beneficiary's attribution status can change during an MY. In other words, to share beneficiary-identifiable data more frequently would require CMS to share data that is not yet final and may be inaccurate. Thus, unlike the data we proposed to share under § 512.390(b)(1), an ETC Participant could not use this interim data to assess CMS's calculation of the MPS.

Comment: One commenter suggested that CMS make available to ETC Participants a list of beneficiaries who are dual-eligible or LIS recipients prospectively (which, in the context of the ETC Model, we interpret to mean in advance of the applicable MY), explaining that sharing such data in advance would give ETC Participants a clearer understanding of their patient population as it will be analyzed by CMS. The commenter also stated that neither the commenter nor healthcare providers are able to fully model the impact of CMS's proposal to stratify achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, as they do not have access to public information regarding ESRD Beneficiaries' LIS eligibility.

Response: As noted previously, under § 512.360, CMS conducts beneficiary attribution retrospectively in the ETC Model, and thus data on the dual eligibility and LIS recipient status of each attributed beneficiary will not be available for CMS to share with ETC Participants prospectively in advance of the MY. Any beneficiary-identifiable

data we could share in advance of an MY would include at least a few beneficiaries that, when we conduct attribution for the MY at the end of that MY, would not be attributed to the ETC Participant, or at least not attributed to the ETC Participant for all months of the MY. Because we conduct beneficiary attribution monthly, attribution is subject to change, and the benefits that the commenter asserts could be gained by CMS sharing dual-eligible and LIS-eligible status data in advance of an MY would likely be undermined by the fact that such data may not be complete or accurate. In other words, CMS cannot know in advance of an MY which beneficiaries, or more specifically, which beneficiary-months, will count for the purpose of conducting attribution and calculating performance; we can only know this after the MY has ended. For this reason, we believe that limiting beneficiary-identifiable data sharing to after the MY, but prior to its corresponding PPA Period—in advance of when the ETC Participant's payments will be adjusted—best ensures that CMS is sharing the most accurate beneficiary-identifiable data as relevant to the ETC Participant's attributed beneficiaries and performance under the ETC Model, while providing the ETC Participant the opportunity to understand and, as needed, request a targeted review of the calculation of the MPS under § 512.390(b) of our regulations. Finally, dual-eligibility and LIS-eligibility data shared prior to a PPA Period could also be viewed as prospective in nature. Specifically, while a beneficiary's attribution status is subject to change during and between MYs, such data will provide ETC Participants with a rough estimate of their population of attributed beneficiaries who are dual-eligible and LIS recipients for the upcoming MY.

Regarding the commenter's concern that neither the commenter nor healthcare providers are able to fully model the impact of CMS's proposal to stratify achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, CMS declines to make beneficiary-identifiable LIS-eligibility data publicly available, or to share with the ETC Participant beneficiary-identifiable LIS-eligibility data on ESRD Beneficiaries who are not attributed to the ETC Participant, as such policies would raise privacy concerns. If the commenter is instead expressing concern that there does not exist publicly available aggregate data regarding ESRD beneficiaries who are LIS-eligible, such broad data dissemination is beyond the scope of this rulemaking for the ETC Model.

Comment: Several commenters provided feedback on the data elements CMS proposed to share with ETC Participants. One commenter expressed support for the data elements that CMS proposed to provide under the ETC Model, noting that, even without claims data, the data CMS proposed to provide would assist ETC Participants in establishing targeted interventions to increase the rates of home dialysis, self-dialysis, and nocturnal in-center dialysis modalities, as well as transplant waitlist rates. The same commenter also recommended that CMS make claims data available to ETC Participants, as claims data would better assist ETC Participants in establishing appropriate care coordination and quality improvement initiatives, thereby improving care for beneficiaries. The commenter also noted that CMS has deemed claims data necessary to share with participants under other models tested under section 1115A of the Act, and that CMS should take the same position here.

Response: We agree that making certain beneficiary-identifiable data available under the ETC Model will help ETC Participants conduct care coordination and quality improvement activities, and realize the goals of the ETC Model of promoting beneficiary choice of renal replacement modality. We believe that our proposal struck the appropriate balance between sharing enough data to ensure that ETC Participants understand which beneficiaries were attributed to them during a given MY for purposes of care management and coordination and quality improvement, providing treatment to the subject beneficiary, and to assess CMS's calculation of the corresponding MPS, while also remaining sensitive to the privacy interests of attributed beneficiaries and sharing only the ''minimum necessary'' amount of beneficiary-identifiable data, as required by the HIPAA Privacy Rule, to support the ETC Model for the purposes we described in the CY 2022 ESRD PPS proposed rule. In most other models tested under section 1115A of the Act under which CMS has made available beneficiary-identifiable Medicare claims data, CMS shares such data only when formally requested by model participants for certain ''health care operations,'' and only after such model participants attest to meeting specific HIPAA requirements, including that the particular claims data requested meet the ''minimum necessary'' for their respective ''health care operations.'' These disclosures are based on the HIPAA Privacy Rule provisions that permit disclosures of PHI for the recipient's health care operations purposes as described in 45 CFR 164.506(c)(4) and § 164.501.

For the ETC Model, we proposed to establish a requirement under § 512.390(b)(1) for CMS to share the beneficiary-identifiable data described in the CY 2022 ESRD PPS proposed rule with ETC Participants. Our proposal did not include a process whereby ETC Participants could request the beneficiary-identifiable data for their ''health care operations.'' As we explained in the CY 2022 ESRD PPS proposed rule (86 FR 36388), having the ETC Participant formally request the beneficiary-identifiable data from CMS would add steps in the process that would cause administrative burden for both CMS and ETC Participants, and operational cost and burden for CMS. We also noted that adding these steps would not produce a meaningful privacy or security benefit based on the specific circumstances of this ETC Model. We agree that Medicare claims data likely would help many ETC Participants' care coordination and quality improvement efforts. However, we do not believe, at this time, that making claims data available is appropriate given the nature of this model, which is focused on making payment adjustments related to relatively specific outcomes, namely increasing rates of home dialysis and transplant. We believe that the data elements we proposed to share with ETC Participants are sufficient to position ETC Participants to meaningfully conduct care coordination and quality improvement activities to increase rates of home dialysis, self-dialysis, nocturnal in-center dialysis, and transplant waitlisting. Moreover, we do not believe that Medicare claims data are necessary for ETC Participants to assess CMS's calculations underlying the payment adjustments made under the ETC Model.

Comment: One commenter recommended that CMS add the following data elements to the beneficiary-identifiable data that CMS would be required to share with ETC Participants: ''Modality attribution status,'' the name of the transplant center at which the beneficiary is listed on the transplant waitlist, and the date on which the beneficiary joined their respective waitlist.

Response: We thank the commenter for this feedback. We believe our proposed data elements capture two of the commenter's three suggested data elements. Specifically, we believe our proposal to provide data on the number

of months the beneficiary was attributed to the ETC Participant, received home dialysis, self-dialysis, or nocturnal in-center dialysis, or was on a transplant waitlist; and the number of months that have passed since the beneficiary has received a living donor transplant, as applicable, sufficiently capture a beneficiary's ''modality attribution status'' (which we interpret to mean the dialysis modality that CMS understands the beneficiary to be receiving) and, even if indirectly, provides the date (or an approximation thereof) that the beneficiary was placed on a transplant waitlist.

CMS did not propose to provide the name of the transplant center at which the beneficiary is listed on the transplant waitlist, and CMS does not believe, at this time, that it is appropriate to make such information available. An ETC Participant should be able to obtain such information from the subject beneficiary, as we anticipate that an ETC Participant would first talk to a beneficiary, and likely obtain the beneficiary's explicit consent, prior to contacting a transplant center on his or her behalf. That said, we may consider this suggestion for future rulemaking related to the ETC Model.

Comment: One commenter suggested that CMS provide more granular data on attributed beneficiaries, and suggested that CMS include the following elements: ''Patient ID,'' ''Date (year/month),'' ''Modality,'' and ''Status (active or not active on transplant list.''

Response: CMS believes that its proposed data elements under § 512.390(b)(1)(ii) capture all of the elements the commenter suggested. CMS proposed sharing the beneficiary's name and MBI, which CMS believes would serve as a ''Patient ID.'' CMS also proposed sharing the number of months a beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and months following a living donor transplant. We believe these data elements capture the ''Date (year/month),'' ''Modality,''modality, and ''Status (active or not active on transplant list'' elements suggested by the commenter. ''Date (year/month)'' could be ascertained by the number of months a beneficiary was attributed to the ETC Participant; ''Modality'' could be ascertained by the beneficiary's data regarding home dialysis months, self-dialysis months, and nocturnal in-center dialysis months; and ''Status (active or not active on transplant list)'' could be ascertained by the transplant waitlist months or months following a living donor transplant.

Comment: Two commenters expressed support for CMS's proposal to provide beneficiary-identifiable data to ETC Participants without establishing a process for ETC Participants to request it. Both commenters asserted that the approach described in the CY 2022 ESRD PPS proposed rule of requiring CMS by law to make available the beneficiary-identifiable data identified in the CY 2022 ESRD PPS proposed rule, rather than allowing ETC Participants to request the data, would decrease burden on both CMS and ETC Participants.

Response: We thank the commenters for their support. We agree that the proposed approach of requiring CMS by law to make available the described beneficiary-identifiable data would reduce burden on both CMS and ETC Participants, and that it is otherwise appropriate for sharing beneficiary-identifiable data under the ETC Model.

Final Rule Action: After considering public comments, we are finalizing our proposal to require in our regulation at § 512.390(b)(1) that CMS make available for retrieval by ETC Participants certain beneficiary-identifiable data no later than one month before the start of each PPA Period, without modification. This beneficiary-identifiable data will include, when available: The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers, dates of birth, dual eligible status, and LIS recipient status; and data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable: The number of months the beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and month following a living donor transplant. As we stated in the CY 2022 ESRD PPS proposed rule, an appropriate Privacy Act system of records ''routine use'' will need to be in place prior to the disclosure of this data.

(1) Conditions for Retrieving Beneficiary-Identifiable Data

Given the sensitive nature of the beneficiary-identifiable data that CMS would be required to share under our proposal, in the CY 2022 ESRD PPS proposed rule (86 FR 36388), we proposed certain conditions for ETC Participants to be able to retrieve this data and certain protections that would govern use of the data following retrieval. First, we proposed that CMS would only share the beneficiary-identifiable data on the condition that the ETC Participant observes all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the HIPAA regulations and agrees to comply with the terms of a separate data sharing agreement. Although we stated that we expected ETC Participants are covered entities and must comply with the HIPAA regulations directly, we proposed to include this provision to ensure an ETC Participant would abide by those rules with respect to the data, even if, for example, the ETC Participant is a hybrid entity under HIPAA and the component requesting the data has not been designated as a health care component under 45 CFR 164.105. We proposed that the HIPAA provisions that the ETC Participant would have to observe would include, but would not be necessarily limited to, standards regarding the use and disclosure of PHI; administrative, physical, and technical safeguards and other security provisions; and breach notification.

We proposed that, if an ETC Participant wishes to retrieve the beneficiary-identifiable data, the ETC Participant would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS, which we would call the ETC Data Sharing Agreement. We proposed that this agreement would include certain protections and limitations on the ETC Participant's use and further disclosure of the beneficiary-identifiable data, and would be provided in a form and manner specified by CMS, which we discussed in more detail in later sections of the CY 2022 ESRD PPS proposed rule and describe below. We also stated that this agreement would potentially require the ETC Participant to make certain attestations, for example, if required under the applicable Privacy Act system of records notice. We proposed that an ETC Participant that wishes to retrieve the beneficiary-identifiable data would be required to complete and submit a signed ETC Data Sharing Agreement at least annually. We stated that we believe that it is important for the ETC Participant to complete and submit a signed ETC Data Sharing Agreement at least annually so that CMS has up-to-date information that the ETC Participant wishes to retrieve the beneficiary-identifiable data, attestations (if required), and information on the designated data custodian(s). As described in greater detail in the CY 2022 ESRD PPS proposed rule (86 FR 36388—36389),

we proposed that a designated data custodian would be the individual(s) that an ETC 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.

In the CY 2022 ESRD PPS proposed rule, we stated our belief that it is important for the ETC Participant to first complete and submit a signed ETC 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 ETC Participant. As described in section V.B.7.b of the CY 2022 ESRD PPS proposed rule and previously in this final 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 ETC Participants would be further protected in an appropriate fashion.

In the CY 2022 ESRD PPS proposed rule, we considered an alternative under which ETC Participants would not need to complete and submit a signed ETC Data Sharing Agreement, but we concluded that, if we proceeded with this option, we would not have adequate assurances that the ETC Participants would appropriately protect the privacy and security of the beneficiary-identifiable data that we are proposing to share with them. We also considered, in the CY 2022 ESRD PPS proposed rule, an alternative under which the ETC Participant would need to complete and submit a signed ETC Data Sharing Agreement only once for the duration of the ETC Model. However, we concluded that this similarly would not give CMS adequate assurances that the ETC Participant would protect the privacy and security of the beneficiary-identifiable data from CMS. We concluded in the CY 2022 ESRD PPS proposed rule that it is critical that we have up-to-date information and designated data custodians, and that requiring the ETC Participant to submit an ETC Data Sharing Agreement at least annually would represent the best means of achieving this goal.

We solicited public comment on our proposal to require, in § 512.390(b)(1)(iii), that the ETC Participant agree to comply with all applicable laws and the terms of the ETC Data Sharing Agreement as a condition of retrieving the beneficiary-identifiable data, and on our proposal in § 512.390(b)(1)(iv) that the ETC Participant would need to submit the signed ETC Data Sharing Agreement at least annually if the ETC Participant wishes to retrieve the beneficiary-identifiable data.

The following is a summary of the comments received on our proposals regarding the conditions for retrieving beneficiary-identifiable data, and our responses.

Comment: Some commenters expressed support for our proposal to require an ETC Participant to complete an ETC Data Sharing Agreement prior to CMS making the beneficiary-identifiable data described in the CY 2022 ESRD PPS proposed rule available to the ETC Participant. One such commenter noted that CMS's proposals strike a good balance between crucial privacy goals and ETC Participants' need to assess their performance under the Model. Another commenter claimed that the proposed process would be consistent with the process CMS followed in the Comprehensive ESRD Care (CEC) Model and is following in the Kidney Care Choices (KCC) Model Options.

Response: We agree that requiring an ETC Participant to complete an ETC Data Sharing Agreement prior to CMS making the beneficiary-identifiable data described in the CY 2022 ESRD PPS proposed rule available to the ETC Participant strikes an appropriate balance between the important goals of making ETC Participants aware of which beneficiaries CMS has attributed to them and enabling ETC Participants to understand the basis by which CMS computed their MPS, while protecting the privacy interests of attributed beneficiaries. We clarify, however, that the process CMS followed in the CEC Model and is following in the KCC Model Options is different from the process CMS proposed for the ETC Model. In the CEC Model CMS offered model participants the opportunity to request beneficiary-identifiable data for their ''health care operations,'' in accordance with HIPAA Privacy Rule provisions at 45 CFR 164.506(c)(4), contingent upon the participants making certain attestations and agreeing to certain privacy and security protections as part of the participation agreements for those models. CMS is taking this same approach with the KCC Model Options. For the ETC Model, we proposed that CMS would be required by law to provide certain beneficiary-identifiable data to ETC Participants, in accordance with the HIPAA Privacy Rule provisions at 45 CFR 164.512(a), contingent upon the ETC Participant annually signing an ETC Data Sharing Agreement.

Comment: One commenter expressed specific support for CMS's proposal to require an ETC Participant to complete an ETC Data Sharing Agreement on an annual basis. A couple of commenters recommended that CMS require the ETC Participant to complete an ETC Data Sharing Agreement only once during the Model. One such commenter further suggested that CMS require an ETC Participant to complete a subsequent ETC Data Sharing Agreement if material changes occur requiring a new agreement, rather than requiring an ETC Participant to complete an ETC Data Sharing Agreement annually. This commenter stated that this approach would align with the approach the Innovation Center takes in certain other alternative payment models, and that annual completion of an ETC Data Sharing Agreement would be overly burdensome for ETC Participants.

Response: We believe that it is appropriate to require the ETC Participant to complete an ETC Data Sharing Agreement on an annual basis. It is critical that CMS guarantees, to the best of its ability, that it always has an up-to-date, completed ETC Data Sharing Agreement from each ETC Participant that wishes to obtain the beneficiary-identifiable data CMS described in the CY 2022 ESRD PPS proposed rule. We believe that requiring the ETC Participant to complete an ETC Data Sharing Agreement annually, rather than only when material changes occur, would better ensure that CMS achieves this goal. Even if CMS were to articulate specific elements of what constitutes a ''material change,'' such a policy would require that an ETC Participant appropriately identify when such a change as occurred and timely notify CMS, and would require CMS to conduct additional monitoring and outreach activities to ensure compliance. Such an approach imposes additional and substantial burden on CMS in the context of the ETC Model, which includes approximately 7,000 ETC Participants, and this burden is disproportionate to the burden imposed on ETC Participants by completing an ETC Data Sharing Form annually. We believe that requiring the ETC Participant to complete an ETC Data Sharing Agreement annually strikes a reasonable balance between ensuring, to the extent possible, that CMS has up-to-date information, while minimizing the administrative burden imposed on a given ETC Participant in completing the form.

While CMS has not required the annual completion of a data sharing agreement in every alternative payment model, the ETC Model importantly

differs from other section 1115A models insofar as participation in the ETC Model changes in a different way than other models. ESRD facilities and Managing Clinicians located in a Selected Geographic Area are required to participate in the ETC Model under § 512.325(a). As such, participation in the ETC Model can fluctuate between MYs when ESRD facilities or Managing Clinicians move in or out of a Selected Geographic Area. This element of the ETC Model differs from many voluntary section 1115A models, such as the CEC Model or Primary Care First, where individuals or entities apply to participate, and accepted individuals or entities continue to participate until the section 1115A model ends or the participant or CMS terminates the participation agreement. The potential fluctuation in participation between MYs creates a need for CMS to require the ETC Participant to complete a data sharing agreement more frequently than it permits or requires in other section 1115A models, and we believe that requiring an ETC Participant to complete the data sharing agreement annually is sufficiently frequent to ensure that CMS has up-to-date data sharing agreements in place.

In addition, other alternative payment models generally provide, within their respective participation agreements, terms and conditions relating to data protection, uses and disclosures, retention, and destruction, and those participation agreements are often amended, which typically requires model participants to complete new data request and attestation forms during the model's performance period. Our CY 2022 ESRD PPS proposed rule indicated that the specific terms relating to privacy, security, data retention, breach notification, and data destruction, which are found for other section 1115A models in the models', governing documentation would be found in the ETC Data Sharing Agreement, and we believe it is important that ETC Participants review these terms at least once a year, including in completing an annual ETC Data Sharing Agreement.

In addition, the ETC Model includes a larger number of participants than many other section 1115A models; as described in the Specialty Care Models final rule, this larger scale is necessary to obtain the minimum sample size needed to produce robust and reliable evaluation results (85 FR 61280). With so many participants receiving beneficiary-identifiable data, CMS believes that the privacy interests of beneficiaries would be best protected by requiring the ETC Participant to complete an ETC Data Sharing Agreement annually, helping CMS to ensure that the ETC Data Sharing Agreement submitted by an ETC Participant is reasonably up-to-date. Moreover, CMS believes that completing an ETC Data Sharing Agreement represents a low burden for an ETC Participant. As discussed later in this final rule, the ETC Data Sharing Agreement form will be available on the same web-based platform as the beneficiary-identifiable and aggregate data, which the ETC Participant likely would be accessing at least twice a year to obtain data when available at least 30 days prior to a PPA Period.

Comment: One commenter recommended that CMS follow its approach in the Kidney Care Choices Model of requiring, in the commenter's words, ''eligible signatories for the ETC Data Sharing Agreement.''

Response: We thank the commenter for this feedback. We agree that it is important that the individual who signs the ETC Data Sharing Agreement has the authority to bind the ETC Participant to its terms and conditions. We believe this is standard for any binding agreement, and thus we do not believe we must specify this in our regulations.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b)(1)(iii) and § 512.390(b)(1)(iv) to require that the ETC Participant observe all applicable laws regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the HIPAA regulations, and agree to comply with the terms of the ETC Data Sharing Agreement, to be signed at least annually, as a condition of receiving the beneficiary identifiable data, with one modification. Specifically, we are making a technical change at § 512.390(b)(1)(iii) to replace the phrase ''HIPAA regulations'' with ''regulations found at 45 CFR parts 160 and 164 promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended'' to clarify the applicable regulations, as the regulations initially promulgated under HIPAA have been amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, and may be amended by other statutes in the future.

(2) Content of ETC Data Sharing Agreement Provisions for Beneficiary-Identifiable Data

We proposed in new § 512.390(b)(iv) that, under the ETC Data Sharing Agreement, ETC Participants would 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 and the requirements of the ETC Model set forth in 42 CFR part 512; (2) to comply with additional privacy, security, and breach notification requirements to be specified by CMS in the ETC Data Sharing Agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the ETC Participant or performs a similar function for the ETC Participant, to the same terms and conditions to which the ETC Participant is itself bound in its data sharing agreement with CMS as a condition of the downstream recipient's receipt of the beneficiary-identifiable data retrieved by the ETC Participant under the ETC Model; and (4) that if the ETC 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 ETC Data Sharing Agreement, the ETC Participant would no longer be eligible to retrieve the beneficiary-identifiable data and may be subject to additional sanctions and penalties available under the law. In the CY 2022 ESRD PPS proposed rule (86 FR 36389), we stated that we believe these terms for sharing beneficiary-identifiable data with ETC Participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ETC Participants would be further protected by the ETC Participant, and any business associates of the ETC Participant, in an appropriate fashion. We stated that we believe that these proposals would allow CMS to accomplish that.

CMS solicited public comment on the additional privacy, security, breach notification, and other requirements that we would include in the ETC Data Sharing Agreement. As we noted in the CY 2022 ESRD PPS proposed rule, 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. We proposed that 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. We additionally proposed that these provisions would not prohibit the ETC Participant from making any disclosure of the data otherwise required by law.

We noted in the CY 2022 ESRD PPS proposed rule that we were considering limiting the use of beneficiary-identifiable data for specific purposes, either alone or in combination. We noted that, for example, in the ETC Data Sharing Agreement, CMS considered imposing limits on how the ETC Participant may use the beneficiary-identifiable data without prior written authorization from CMS to specific purposes, such as assessing CMS's calculation of the MPS for a given PPA Period, the ETC Participant's clinical care or ''treatment'' (as that term is defined at 45 CFR 164.501) of an attributed beneficiary, and certain ''health care operations'' (as that term is defined at 45 CFR 164.501) of the ETC Participant. As noted previously in the CY 2022 ESRD PPS proposed rule and this final rule, CMS believes that ETC Participants would require this data to be able to request a targeted review of CMS's calculation of the MPS as it relates to a given PPA Period, as understanding and being able to seek review of CMS's calculation of the MPS, and thus the reason CMS adjusted the ETC Participant's Medicare payments in the manner it did, is critical for the ETC Model. In the CY 2022 ESRD PPS proposed rule, we noted that importantly, there is no other source of this information outside of CMS. In addition to potentially limiting use to reviewing how CMS calculated the ETC Participant's MPS, we stated in the CY 2022 ESRD PPS proposed rule that we were considering limiting, in the ETC Data Sharing Agreement, use of the beneficiary-identifiable data without prior written authorization from CMS to use for clinical treatment purposes. We stated our belief that this beneficiary-identifiable data would be important in helping the ETC Participant determine which of its ESRD Beneficiaries are not on the transplant waitlist or have not received a living donor transplant, to inform how the ETC Participant engages in clinical care of the subject ESRD Beneficiary.

In addition to the previous two uses, we stated in the CY 2022 ESRD PPS proposed rule that we also were considering limiting, in the ETC Data Sharing Agreement, the ETC Participant's use of the beneficiary-identifiable data without prior written authorization from CMS to care management and coordination, quality improvement activities, and provider incentive design and implementation, to the extent these activities would constitute ''health care operations'' that fall within the first and second paragraphs of the definition of that phrase under the HIPAA Privacy Rule (45 CFR 164.501). As it relates to case management and coordination and quality improvement activities, we stated in the CY 2022 ESRD PPS proposed rule that CMS believes that this beneficiary-identifiable data would help the ETC Participant to conduct the important task of identifying which ESRD Beneficiaries are not currently on the transplant waitlist and thus better enable the ETC Participant to engage those beneficiaries, as clinically appropriate, about the process of signing up for the transplant waitlist, thereby improving the ETC Participant's performance on the transplant waitlist rate, and increasing the likelihood that the subject ESRD Beneficiaries would receive a transplant. In addition, we noted our belief that sharing this data with the ETC Participant would help the ETC Participant to conduct the important task of identifying which ESRD Beneficiaries are receiving dialysis in-center, and to consider whether furnishing kidney disease patient education services or otherwise making such beneficiaries aware of the possibility of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, as clinically appropriate in the ESRD Beneficiary's individual situation.

We sought public comment on how an ETC Participant might need to, and want to, use the beneficiary-identifiable data retrieved from CMS under the ETC Model to accomplish the goals of the ETC Model in accordance with applicable law.

We also sought public comment on what further disclosures of the beneficiary-identifiable data might be appropriate to permit or prohibit under the ETC Data Sharing Agreement. For example, we stated in the CY 2022 ESRD PPS proposed rule that CMS considered prohibiting, in the ETC Data Sharing Agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data described previously in this section of the CY 2022 ESRD PPS proposed rule 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 subject ESRD Beneficiary or Pre-emptive LDT 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 beneficiary-identifiable data with model participants. In the alternative, we noted, CMS also considered including more restrictive prohibitions in the ETC Data Sharing Agreement, which would limit further discloses to only some, one, or none of the categories of individuals or entities described above.

We explained in the CY 2022 ESRD PPS proposed rule that we considered all of these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data discussed previously in the CY 2022 ESRD PPS proposed rule, and CMS must consider carefully the ways in which and reasons for which we would provide access to this data for purposes of the ETC Model. We stated that we believe that some ETC 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 ETC Participant's review of CMS's MPS calculations, care management and coordination, quality improvement activities, or clinical treatment of attributed beneficiaries. We further noted that we believe that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the subject ESRD Beneficiary or Pre-emptive LDT Beneficiary.

We sought public comment on how an ETC Participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the ETC Model, in accordance with applicable law.

Under our proposal, the ETC Data Sharing Agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, we considered including, in the ETC Data Sharing Agreement, a requirement that the ETC 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 ETC Data Sharing Agreement; various security requirements like those found in 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 ETC 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. We noted that these are only examples, and are not the only terms CMS would potentially include in the ETC Data Sharing Agreement.

We solicited public comment on this proposal that CMS, by adding § 512.390(b)(1)(iv)(B), would impose certain requirements in the ETC Data Sharing Agreement related to privacy, security, data retention, breach notification, and data destruction.

Finally, as described previously in section V.B.7.b(2) of this final rule, we proposed, at § 512.390(b)(1)(iv)(D), that the ETC Data Sharing Agreement would include a term providing that if the ETC 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 ETC Data Sharing Agreement, the ETC Participant would no longer be eligible to retrieve beneficiary-identifiable data under proposed § 512.390(b)(1)(i) and may be subject to additional sanctions and penalties available under law. We also proposed to make conforming amendments to 42 CFR 512.160. Section 512.160(b) outlines the remedial actions available under the RO Model and ETC Model, and paragraph (b)(8), in particular provides that, if CMS determines that one or more grounds for remedial action specified in § 512.160(a) has taken place, CMS may discontinue the provision of data sharing and reports to the model participant. We proposed to add a new § 512.160(a)(9) to specify that, for the ETC Model only, CMS may take remedial action if the model 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 applicable data sharing agreement. We noted that this proposed change would align the regulatory provision on remedial action with the remedial action we would include in the ETC Data Sharing Agreement.

We solicited public comment on this proposal, to prohibit the ETC Participant from obtaining beneficiary-identifiable data pertaining to the ETC Model if the ETC Participant fails to comply with applicable laws and regulations, the terms of the ETC Model, or the ETC Data Sharing Agreement.

The following is a summary of the comments received on additional privacy, security, breach notification, and other requirements that we proposed to include in the ETC Data Sharing Agreement, and our responses.

Comment: One commenter expressed general support for having strong safeguards to protect sensitive beneficiary information and to ensure the data's appropriate use.

Response: We appreciate this comment. We agree that it is critical that any data sharing policy we finalize for the ETC Model have strong safeguards designed to protect sensitive beneficiary information and to ensure, to the best of our ability, the appropriate use of the data by ETC Participants and their downstream users.

Comment: One commenter expressed support for allowing an ETC Participant to disclose the beneficiary-identifiable data shared by CMS under the ETC Model with other covered entities in a treatment relationship with ESRD Beneficiaries, and with the ETC Participant's business associates. The commenter noted that this proposal would allow the data to be used in quality improvement activities by ETC Participants, and that many clinicians partner with third-party data vendors as business associates under the HIPAA rules, since such vendors have expertise in the field of data analytics and in analyzing trends and identifying areas for quality improvement.

Response: CMS agrees that it is appropriate to allow an ETC Participant to disclose the beneficiary-identifiable data shared by CMS under the ETC Model with other covered entities in a treatment relationship with ESRD Beneficiaries, to help ensure that other covered entities who furnish care to ESRD Beneficiaries have the benefit of this important information related to the subject beneficiary's kidney care. In addition, CMS agrees that many clinicians contract with third parties for analytics support, and that such support can assist clinicians in conducting quality improvement activities. As we describe later in this section of the final rule, CMS is finalizing a data sharing policy that will allow an ETC Participant to disclose the beneficiary-identifiable data shared by CMS under the ETC Model with a business associate of the ETC Participant, so long as the ETC Participant contractually binds the business associate to the same terms and conditions to which the ETC Participant is itself bound in its ETC Data Sharing Agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data. The policy we are finalizing places limits on the ETC Participant's further disclosures of the beneficiary-identifiable data shared by CMS. Specifically, the policy we are finalizing requires that any non-covered entity with whom the ETC Participant discloses beneficiary-identifiable data made available to the ETC Participant under the ETC Model must be a business associate of the ETC Participant—and cannot be a downstream recipient who is neither a covered entity nor a business associate of the ETC Participant—except as otherwise required by law. CMS is making this modification because it believes that limiting downstream recipients of beneficiary-identifiable data shared under the ETC Model to those who have a business associate agreement in place with the ETC Participant, and that business associate agreement adopts the terms required under this regulation, will best safeguard the privacy and security interests of beneficiaries.

Comment: One commenter expressed support for the data shared to be protected by existing Federal privacy and confidentiality laws, but requested that CMS clarify the differences between the privacy protections required under the ETC Model and those required by HIPAA.

Response: It is critical to clarify that the policies we are finalizing in this section of the final rule are for the ETC Model only and are not intended to modify the HIPAA Privacy Rule or change existing legal obligations under the HIPAA Privacy Rule or other privacy laws. By finalizing our proposal in this final rule, we are establishing a requirement under § 512.390(b)(1) for CMS to share beneficiary-identifiable data in a manner that is consistent with the HIPAA Privacy Rule, 45 CFR 164.512(a). We are also establishing additional protections for the beneficiary-identifiable data shared with ETC Participants under the ETC Model that they must, in turn, impose on any business associates. These additional requirements and safeguards include, but are not limited to, the annual completion and submission of an ETC Data Sharing Agreement; specific instructions relating to breach notification and data retention and destruction; and the identification of one or more data custodians who will be responsible for ensuring compliance with the privacy, security, and breach notification requirements set forth in the ETC Data Sharing Agreement. Further, under our final policy, we are placing additional limits on how the ETC Participant may use and further disclose the beneficiary-identifiable identifiable data received from CMS under the ETC

Model, beyond what may otherwise be permitted under the HIPAA Privacy Rule. In particular, ETC Participants will be limited to using and further disclosing the beneficiary-identifiable data under the ETC Model for the following purposes (other than disclosures otherwise required by law), without obtaining prior written permission from CMS: The ETC Participant's ''health care operations'' that fall within the first and second paragraphs of the definition of that phrase under the HIPAA Privacy Rule (45 CFR 164.501), to the extent they relate to care management and coordination, quality improvement activities, and provider incentive design and implementation; for clinical care or ''treatment'' (as that term is defined in 45 CFR 164.501) of the subject beneficiary; and for assessing CMS's calculations underlying the MPS for the relevant PPA Period. We believe these uses and bases for further disclosure represent the only appropriate uses and bases for further disclosure for the beneficiary-identifiable data made available to the ETC Participant under the Model, and the only appropriate uses for business associates to whom the ETC Participant discloses such data, for the reasons we provide below in response to other comments.

Comment: One commenter recommended that CMS not impose additional restrictions on data sharing beyond those required by the HIPAA Privacy Rule, and asserted that an ETC Participant should be able to use the beneficiary-identifiable data for the same ''treatment'' and ''health care operations'' activities permitted under HIPAA. Another commenter similarly suggested that CMS not impose additional limitations on an ETC Participant's use or further disclosure of the beneficiary-identifiable data beyond those imposed by existing law, and additionally recommended that CMS not require the ETC Participant to obtain permission from CMS or another agency prior to any permitted data use.

Response: We agree that an ETC Participant should be able to use the beneficiary-identifiable data made available by CMS under the ETC Model for the ''treatment'' (as that term is defined in 45 CFR 164.501) of the subject beneficiary, and we are finalizing our proposal to allow an ETC Participant to use such data for treatment. We believe it is important that an ETC Participant be able to use such data to inform their direct care of the beneficiary, especially as it relates to discussing renal replacement modalities and transplantation.

The definition of ''health care operations'' in the HIPAA Privacy Rule at 45 CFR 164.501 covers a broad array of activities, most of which we believe are not relevant or necessary for purposes of the ETC Participant's performance in the Model. For example, an ETC Participant would not need to perform ''underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits[,]'' as described in the third paragraph of the definition. In addition, other uses and disclosures generally allowed under HIPAA without obtaining individual authorization, such as ''payment,'' are not relevant to the ETC Participant's performance in the Model. To appropriately safeguard the beneficiary-identifiable data, we will limit the permitted uses and further disclosures of the PHI shared under the ETC Model to the ETC Participant's ''health care operations'' that fall within the first and second paragraphs of the definition of that phrase under the HIPAA Privacy Rule (45 CFR 164.501), to the extent they relate to care management and coordination, quality improvement activities, and provider incentive design and implementation; treatment of the subject beneficiary; assessing CMS's calculations of the ETC Participant's MPS; and as otherwise required by law. In addition, under our final policy, we will permit the ETC Participant to use and further disclose beneficiary-identifiable retrieved under the ETC Model for assessing CMS's calculations underlying the MPS, which sufficiently covers the ETC Participant's need to use such data for ''[b]usiness planning and development'' as permitted under the fifth paragraph of the ''health care operations'' definition.

Moreover, we agree that it is not desirable to require an ETC Participant to obtain permission from CMS or another agency prior to engaging in any particular use or further disclosure of the beneficiary-identifiable data. Once the ETC Participant has completed its annual ETC Data Sharing Agreement, we do not expect the ETC Participant will need to obtain additional permission from CMS or another agency to use or further disclose the beneficiary-identifiable data in the ways we describe in this final rule or will describe in the ETC Data Sharing Agreement, or that CMS may otherwise authorize in writing.

Comment: One commenter recommended that CMS implement a warning system prior to deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data under the ETC Model, because without access to the beneficiary-identifiable data that CMS proposed to make available to ETC Participants under the Model, an ETC Participant would be unable to identify its dual-eligible or LIS-eligible beneficiaries, or trends in the data for the purpose of conducting quality improvement. The commenter additionally asserted that rendering an ETC Participant ineligible to retrieve such data would lead to a decrease in the quality of care provided, negatively affecting both ETC Participants and attributed beneficiaries. The commenter further suggested that an instance of noncompliance with the relevant requirements under the proposed regulation at § 512.390(b) or the ETC Data Sharing Agreement could arise due to an inadvertent error.

Response: We thank the commenter for this feedback. As we noted in the CY 2022 ESRD PPS proposed rule and in this section of this final rule, there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and we must ensure to the best of our ability that any beneficiary-identifiable data shared with ETC Participants would be further protected in an appropriate fashion. Further, errors or other conduct resulting in the improper disclosure of beneficiary-identifiable data, inadvertent or otherwise, threaten the privacy interests of attributed beneficiaries. However, we also understand that not every improper use, disclosure, or other handling of beneficiary-identifiable data shared under the ETC Model would equally threaten the privacy interests of attributed beneficiaries. We agree with the commenter that we should retain a level of discretion in responding to instances of noncompliance.

However, we disagree that we should implement an explicit warning system prior to deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data under the ETC Model. If CMS believed that a given instance of noncompliance warranted a warning, CMS would have discretion under § 512.160 to impose various remedial actions, including but not limited to notifying the ETC Participant of the violation. We also have the discretion under § 512.160 to require the ETC Participant to provide additional information to CMS or its designees; subject the model participant to additional monitoring, auditing, or both; or to require the ETC Participant to submit a corrective action plan. In other words, CMS already has the authority impose remedial actions less severe than discontinuing data sharing, if CMS

determines the situation so warranted, without implementing an explicit warning system that would impose burden and limit CMS's discretion. Accordingly, we decline to implement an explicit warning system prior to deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data under the Model.

Instead, we are finalizing § 512.390(b)(1)(iv)(D) with a modification to grant CMS more discretion in determining whether an ETC Participant's misuse or improper disclosure of beneficiary-identifiable data warrants CMS deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data during performance of the Model. Under this modification, CMS may deem an ETC Participant ineligible to retrieve such data for any amount of time, meaning it could be for the entire period of the Model or for a shorter time, or CMS could impose a lesser remedial action. This language would better align with our proposal to add a new § 512.160(a)(9) to specify that, for the ETC Model only, CMS may take remedial action under § 512.160(b) if CMS determines that the model 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 applicable data sharing agreement.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b)(iv)(A)–(D) related to additional privacy, security, breach notification, and other requirements that we would include in the ETC Data Sharing Agreement, with modification. First, we are modifying our proposal at § 512.397(b)(iv)(C) to remove language related to downstream recipients who perform a similar function or service to that of a business associate, to clarify that the ETC Participant may only further disclose beneficiary-identifiable data made available under the ETC Model to business associates of the ETC Participant. Second, we are modifying our proposed policy that an ETC Participant that misuses or discloses the beneficiary-identifiable data retrieved under the ETC Model in a manner that violates any applicable statutory or regulatory requirements, or that is otherwise noncompliant with the provisions of the ETC Data Sharing Agreement, would be automatically ineligible to retrieve beneficiary-identifiable data under the ETC Model. Instead, we are finalizing a policy that would give CMS discretion to take appropriate remedial action in the instance that an ETC Participant engages in such misuse or improper disclosure. Specifically, we are modifying the proposed language at § 512.390(b)(1)(iv)(D) to provide that, if an ETC Participant wishes to retrieve the beneficiary identifiable data specified in § 512.390(b)(1)(ii), the ETC Participant agrees, in signing and completing the ETC Data Sharing Agreement, that if the ETC 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 deem the ETC Participant ineligible to retrieve the beneficiary-identifiable data under § 512.390(b)(1)(i) for any amount of time, and the ETC Participant may be subject to additional sanctions and penalties available under the law. We are otherwise finalizing our proposal to include privacy, security, breach notification, and other requirements in the ETC Data Sharing Agreement.

(3) Process for Retrieving the ETC Data Sharing Agreement and Beneficiary-Identifiable Data

In the CY 2022 ESRD PPS proposed rule (86 FR 36390), we proposed that we would make the ETC Data Sharing Agreement and beneficiary-identifiable data available in a form and manner specified by CMS. We stated that we expected to provide a web-based platform for ETC Participants to use to retrieve the beneficiary-identifiable data. We noted that CMS would provide ETC Participants further information about this web-based platform through the ETC listserv and the ETC Model website at a date to be determined by CMS, but at least 1 month before the first PPA Period begins on June 1, 2022. We also stated that we expect that CMS would notify ETC Participants of each opportunity to retrieve a new set of beneficiary-identifiable data and the process for accessing the web-based platform to receive the data through the ETC listserv and on the ETC Model website. Under this proposal, the ETC Participant would be required to use the form and manner specified by CMS (which we expect will be a web-based platform) to retrieve the data. We proposed that if the ETC Participant did not use the form and manner specified by CMS or did not agree to the ETC Data Sharing Agreement, the ETC Participant would be unable to retrieve the beneficiary-identifiable data described previously in this section of the CY 2022 ESRD PPS proposed rule. We proposed that ETC Participants would be permitted to retrieve this data at any point during the relevant PPA Period. In the CY 2022 ESRD PPS proposed rule, we considered establishing certain periods of time within a PPA Period during which the ETC Participant would be able to retrieve the data, but we concluded that permitting the ETC Participant to obtain the data at any point during the relevant PPA Period would be relatively operationally low-burden for CMS while providing additional flexibility to the ETC Participant.

We stated that we believe that it is important that the ETC Participant complete and submit its signed ETC Data Sharing Agreement, and retrieve the beneficiary-identifiable data, in the same form and manner (which we expect to be a web-based platform).

In the alternative, we considered providing the beneficiary-identifiable data to ETC Participants via paper mail rather than through a web-based platform, but we concluded that making the data available through a web-based platform would reduce administrative burden on both CMS and the ETC Participants. We also concluded that making this beneficiary-identifiable data available through a web-based platform would allow CMS to provide the data in a manner that is more secure than if CMS were to make the data available through paper mail. As we explained in the CY 2022 ESRD PPS proposed rule, by using a web-based platform, to be further described by CMS through the ETC listserv and the ETC Model website, CMS would help ensure that only authorized users would be able to obtain the data, and would be able to implement a two-factor authentication to help ensure that no one other than an ETC Participant would have access to the data. In addition, we concluded that it would be more efficient to provide the ETC Data Sharing Agreement and the beneficiary-identifiable data itself through the same form and manner (which we expect to be a web-based platform), rather than using two different processes and that using a web-based platform would be more efficient than paper mail. For these reasons, we stated that we believe the best option would be for us to use only the web-based platform both for providing the ETC Data Sharing Agreement and for sharing data pertaining to the ETC Model.

We solicited public comment on our proposal to require the ETC Participant to complete and submit a signed ETC Data Sharing Agreement before the ETC Participant could retrieve the beneficiary-identifiable data, and on our

proposal that the ETC Participant would be required to retrieve the beneficiary-identifiable data in the same form and manner as the ETC Participant receives and submits the ETC Data Sharing Agreement. We also solicited comment regarding our expectation that we will use a web-based platform, rather than paper mail, for these purposes.

The following is a summary of the comments received on our proposed process for retrieving the ETC Data Sharing Agreement and beneficiary-identifiable data, and our responses.

Comment: Two commenters expressed support for CMS making the beneficiary-identifiable data available to the ETC Participant via a web-based platform. One such commenter expressed opposition to the alternative process that CMS considered; namely, to share the beneficiary-identifiable data via paper mail, as data sent via paper mail would be inconvenient to both CMS and ETC Participants. The commenter also stated that sharing the beneficiary-identifiable data by paper mail would increase the risk of the data being viewed by the wrong parties, and that mailing data would be contradictory to CMS's initiatives promoting interoperability.

Response: We agree that a web-based platform is an appropriate process for sharing beneficiary-identifiable data in the ETC Model, and is a more appropriate process than sharing such data through paper mail. We believe, as we expressed in the CY 2022 ESRD PPS proposed rule, that making the data available through a web-based platform would reduce administrative burden on both CMS and ETC Participants, and that a web-based platform would be more secure than making the data available through paper mail. We agree with the commenter's concern that sharing data via paper mail would increase the risk of a data breach compared to sharing data via a web-based platform. While we do not believe sharing data via paper mail would necessarily contradict CMS's efforts promoting interoperability, we do believe that sharing data via paper mail would make it more burdensome for ETC Participants to ingest the data in a software that could exchange information with other healthcare providers or suppliers, or business associates, as appropriate.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b) that an ETC Participant must obtain an ETC Data Sharing Agreement, sign and complete an ETC Data Sharing Agreement, and retrieve beneficiary identifiable data all in a form and manner to be specified by CMS, without modification. As stated in the CY 2022 ESRD PPS proposed rule, we expect that ''form and manner'' will be via a web-based platform, and CMS will provide ETC Participants further information about this web-based platform via the ETC listserv and ETC Model website at least one month before the first PPA Period begins on June 1, 2022.

e. CMS Sharing of Aggregate Data

In addition to the proposed process for sharing beneficiary-identifiable data described previously in this section, we proposed in § 512.390(b)(2) that CMS would make available certain aggregate data for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period. We proposed that this aggregate performance data, would include, when available, the following information for each PPA Period, de-identified in accordance with 45 CFR 164.514(b): The ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and, if finalized, Health Equity Incentive; the ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and, if finalized, Health Equity Incentive; information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark (that is, whether the ETC Participant met or exceeded the threshold for each such benchmark); and the ETC Participant's MPS and PPA for the corresponding PPA Period. We stated in the CY 2022 ESRD PPS proposed rule (86 FR 36391) that we believe sharing this aggregate, de-identified data with the ETC Participant would be important to help the ETC Participant better understand its performance in the ETC Model relative to its aggregation group and to the achievement and improvement benchmarks against which CMS is measuring the ETC Participant's performance. We stated that whereas the beneficiary-identifiable data described previously in the CY 2022 ESRD PPS proposed rule and this section of the final rule would indicate which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries the ETC Participant could devote greater resources to, CMS believes this aggregate, de-identified data would better enable the ETC Participant to see which performance rates the ETC Participant might need to improve to more generally improve its performance under the ETC Model.

We proposed that CMS would make this data available to the ETC Participant for retrieval in a form and manner to be specified by CMS no less than one month prior to each PPA Period. We stated that we expected that CMS would make this data available to the ETC Participant on the same web-based platform on which CMS would be providing the beneficiary-identifiable data described previously in this section. We proposed that the ETC Participant would be required to use the form and manner specified by CMS to retrieve this aggregate data, but would not have to agree to the ETC Data Sharing Agreement to retrieve this aggregated data, as it is not beneficiary-identifiable. We noted our belief that using a web-based platform for sharing this aggregate data would be appropriate for the same reasons it would be appropriate for sharing the beneficiary-identifiable data. By using a web-based platform, CMS would help ensure that only authorized users would be able to obtain the data, and would be able to implement a two-factor authentication to help ensure that no one other than an ETC Participant would have access to the data. In addition, we stated, because CMS would be providing the ETC Data Sharing Agreement and beneficiary-identifiable data on the same web-based platform, we believe it would be convenient for the ETC Participant if CMS shared the aggregate data on the same web-based platform.

In the alternative, we considered sending this aggregate data to the ETC Participant via paper mail. However, CMS concluded in the CY 2022 ESRD PPS proposed rule that it would be more convenient to the ETC Participant to retrieve this data from a web-based platform rather than via paper mail, and that sending this data via paper mail would represent significant administrative and operational burdens for CMS.

We solicited public comment on our proposal to share aggregate data generally, to share aggregated data in the same form and manner we are proposing to use for sharing beneficiary-identifiable data. We also solicited public comment on our expectation to use a web-based platform for this purpose, as well as our considered alternative to share the aggregate data via paper mail.

The following is a summary of the comments received on our proposed process for sharing aggregate data, and our responses.

Comment: Some commenters expressed support for our proposal to

share aggregate data. One such commenter stated that aggregate data will help an ETC Participant determine its previous rates for different dialysis modalities, and allow the ETC Participant to focus on increasing rates of the dialysis modalities measured for payment adjustments under the ETC Model. The commenter further noted that without knowledge of the ETC Participant's current rates on the different modalities, the ETC Participant would have difficulty understanding when the ETC Participant's actions have resulted in positive change. Another commenter noted that many small ETC Participants may lack the resources to perform detailed analytics with the beneficiary-identifiable data, and that the proposed aggregate data would thus be helpful for such ETC Participants. The same commenter additionally noted that the proposed aggregate data would be useful for ETC Participants that can and do perform detailed analytics with the beneficiary-identifiable data to help validate the results of such analytics.

Response: We agree that sharing the aggregate data, as proposed, would prove helpful for ETC Participants, regardless of the individual ETC Participant's analytics capacity. We also agree that such data can be used to compare the ETC Participant's previous home dialysis and transplant rates, and performance with current rates and performance, and thus can help signal to the ETC Participants when interventions are producing positive results.

Comment: One commenter expressed support for our proposal to not require the ETC Participant to sign an ETC Data Sharing Agreement to obtain aggregate data from CMS.

Response: We agree; we do not believe an ETC Data Sharing Agreement is necessary to protect the aggregate data because it will be fully de-identified in accordance with HIPAA requirements under 45 CFR 164.514(b) and will not contain any beneficiary-identifiable data.

Comment: One commenter recommended that CMS make available aggregate comparative data to ETC Participants quarterly to allow an ETC Participant to assess where it stands on its home dialysis rate and transplant rate in terms of ranking relative to other ETC Participants' performance.

Response: We appreciate this comment. For the same reason that we are not making beneficiary-identifiable data available on a more frequent cadence as discussed in section V.B.7.b of this final rule, we are not making aggregate data available on a more frequent cadence. Specifically, we believe that the proposed schedule for sharing aggregate data affords the ETC Participant sufficient time to derive benefit, such as monitoring the ETC Participant's performance over the course of the ETC Model from the aggregate data. Further, as described in § 512.360, CMS conducts beneficiary attribution for each month retrospectively after the end of each MY, at which time CMS calculates the ETC Participant's MPS. Accordingly, CMS would not have aggregate data to share with the ETC Participant on a quarterly basis; CMS is unable to share aggregate data on the ETC Participant's performance more often than biannually, after the end of the applicable MY.

In addition, we do not believe it is necessary for CMS to release aggregate comparative data to ETC Participants at this time. As described in § 512.370(b), to assess the ETC Participant's achievement score, CMS assesses the ETC Participant performance at the aggregation group level against benchmarks constructed among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. The beneficiary-identifiable data we proposed to share includes the ETC Participant's MPS, and the aggregate data we proposed to share includes information on how the ETC Participant's and the ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark. In this way, the data CMS is already planning to share will provide the ETC Participant with insight into how the ETC Participant and the ETC Participant's aggregation group performed relative to other health care providers in the corresponding Comparison Geographic Area during the applicable Benchmark Year.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b)(2) to share aggregate data and to specify the aggregate data that CMS would share and the process by which CMS would make available and the ETC Participant would obtain such aggregate data, without modification. Specifically, we are finalizing our proposal to require CMS to share make aggregate data available for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period. This de-identified data includes, when available, the ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and the Health Equity Incentive; the ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, and living donor transplant rate, and the Health Equity Incentive; information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark; and the ETC Participant's MPS and PPA for the corresponding PPA Period.

8. Medicare Waivers and Additional Flexibilities

a. Background on Kidney Disease Patient Education Services Waiver

Pursuant to section 1861(ggg)(1) of the Act and § 410.48 of our regulations, Medicare Part B covers outpatient, face-to-face kidney disease patient education services provided by certain qualified persons to beneficiaries with Stage IV chronic kidney disease. As noted in the Specialty Care Models final rule, kidney disease patient education services play an important role in educating patients about their kidney disease and to help them make informed decisions on the appropriate type of care and/or dialysis needed for them (85 FR 61337). In addition, we noted in the Specialty Care Models final rule that kidney disease patient education services are designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access (85 FR 61337). Because kidney disease patient education services have been infrequently billed, we found it necessary for purposes of testing the ETC Model to waive select requirements of kidney disease patient education services authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Specifically, to broaden the availability of kidney disease patient education services under the ETC Model, we have used our authority under section 1115A(d) of the Act to waive certain requirements for individuals and entities that furnish and bill for kidney disease patient education services. We codified these waivers at § 512.397(b). These include waivers to allow more types of beneficiaries to have access to kidney disease patient education services, as well as greater flexibility in how the kidney disease patient education services are performed. For instance, CMS waived the requirement that kidney disease patient education services are covered only for Stage IV chronic kidney disease (CKD) patients to permit beneficiaries to receive kidney disease patient education

services if they are diagnosed with CKD Stage V or are in the first 6 months of starting dialysis to receive the benefit. CMS also waived the requirements in section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) and (c)(2)(i) of the applicable regulations pertaining to the definition of ''qualified person'' such that registered dieticians/nutrition professionals, licensed clinical social workers, or a clinic/group practice may furnish kidney disease patient education services under the direction of, and incident to the services of a Managing Clinician who is an ETC Participant.

Finally, CMS waived two requirements relating to the content of kidney disease patient education services furnished to a beneficiary. CMS waived the requirement under § 410.48(d)(1) of our regulations that the content of kidney disease patient education services include the management of co-morbidities, including delaying the need for dialysis, when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary. In addition, CMS waived the requirement under § 410.48(d)(5)(iii) of our regulations that an outcomes assessment designed to measure beneficiary knowledge about chronic kidney disease and its treatment be performed during one of the kidney disease patient education services, requiring instead that such outcomes assessment is performed within 1 month of the final kidney disease patient education services session furnished by qualified staff.

b. Kidney Disease Patient Education Services Telehealth Waiver and Additional Flexibilities

Many changes took place in 2020 and early 2021 due to the COVID–19 PHE. Legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We established several flexibilities to accommodate these changes in the delivery of care. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we temporarily waived the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act. For example, CMS waived the rural area requirement at section 1834(m) of the Act to allow for telehealth services, including kidney disease patient education services that can be furnished via telehealth, to be furnished to beneficiaries in any geographic area, regardless of location and in their homes, for the duration of the PHE. These waivers are set to terminate at the end of the COVID–19 PHE.

In the CY 2022 ESRD PPS proposed rule, we stated that we believe that, once the PHE ends, these waivers removing the geographic and site of service originating site restrictions for kidney disease patient education services furnished via telehealth would be necessary solely for purposes of testing the ETC Model (86 FR 36392). Except under very limited circumstances, under section 1834(m) of the Act and its implementing regulations, the originating site where the beneficiary is located at the time a telehealth service is furnished is limited to certain, mostly rural, geographic locations and a site of service that is one of certain types of health care facilities. We also stated our belief that allowing qualified staff to furnish kidney disease patient education services via telehealth, regardless of the beneficiary's geographic area or the site of the beneficiary, and regardless of the site of service of the practitioner, would increase access to kidney disease patient education services for a few reasons. First, some beneficiaries may not have access to reliable transportation, especially those beneficiaries who suffered economically during the ongoing PHE, but may have access to the technology necessary for practitioners to furnish kidney disease patient education services. Moreover, some beneficiaries, even those with reliable transportation, may be more comfortable receiving kidney disease patient education services via telehealth rather than appearing in person after over a year of social distancing, even when it becomes safe according to Federal guidance for such beneficiaries to enter physical spaces with other individuals. We noted that this is especially likely to be the case for instances in which a practitioner would furnish kidney disease patient education services in a group session rather than an individual session. We further noted that increasing access to kidney disease patient education services is consistent with one of the main goals of the ETC Model, insofar as we believe that education, as delivered through kidney disease patient education services, helps improve beneficiary choice of dialysis modality.

In addition, we stated that we believe that removing beneficiary cost barriers for kidney disease patient education services would be helpful. As we demonstrate below in this final rule, there is a significant relationship between household income or poverty status and kidney disease, and removing or mitigating cost barriers to access to kidney disease patient education services would likely increase the number of beneficiaries who would be willing to receive kidney disease patient education services.

We therefore proposed that, starting in MY3, kidney disease patient education services may be furnished to certain beneficiaries via telehealth in a manner that is more flexible than that required under existing telehealth requirements. In addition, we proposed to permit the reduction or waiver of coinsurance for the kidney disease patient education services, starting in MY3.

(1) Kidney Disease Patient Education Services Telehealth Waiver

CMS proposed to amend § 512.397 to add a waiver of certain telehealth requirements to provide qualified staff, as we proposed to define for purposes of the ETC Model at § 512.310 as described below, the flexibility to furnish kidney disease patient education services via telehealth for the reasons described above (86 FR 36392). Specifically, we proposed to waive the geographic and site of service originating site requirements in sections 1834(m)(4)(B) and 1834(m)(4)(C) of the Act, and in our regulations at 42 CFR 410.78(b)(3) and (4), for kidney disease patient education services furnished via telehealth. We stated, in the CY 2022 ESRD PPS proposed rule, that we believe the kidney disease patient education services telehealth waiver would allow more Medicare beneficiaries to receive kidney disease patient education services via telehealth by removing the originating site restrictions, thus allowing for the beneficiary to be located anywhere, and including at a site not specified in § 410.78(b)(3) of our regulations; and by allowing for the beneficiary to be located outside of a rural area. We also proposed to waive the requirement in section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) such that CMS would not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations under this proposed waiver, if finalized. However, we did not propose to waive the requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an ''interactive telecommunications system,'' as that term is defined in § 410.78(a)(3) to mean multimedia communications equipment

that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Accordingly, we proposed that we would continue to require that the kidney disease patient education services furnished via telehealth be provided through an interactive telecommunications system; audio-only telehealth services would not be permitted.

We proposed that kidney disease patient education services could be furnished via telehealth only by qualified staff. We noted, in the CY 2022 ESRD PPS proposed rule, that we used the terms ''clinical staff'' and ''qualified staff'' in the Specialty Care Models final rule, but did not provide definitions of these terms. For clarity, we proposed to define ''clinical staff'' and ''qualified staff'' in 42 CFR 512.310. We proposed to define ''clinical staff'' to mean a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. We proposed to define the term clinical staff in this manner to describe those clinicians who are authorized to furnish kidney disease patient education services only pursuant to the waiver specified at § 512.390(b)(1)—namely licensed social workers and registered dieticians/nutrition professionals. The remaining clinicians currently specified in § 512.390(b)(1)—doctors, physician assistants, nurse practitioners, and clinical nurse specialists—fall within the existing definition of qualified person at 42 CFR 410.48(a). We therefore proposed to define ''qualified staff'' to mean both clinical staff and any qualified person (as defined at § 410.48(a) of our regulations) who is an ETC Participant.

We sought comment on our proposal to waive the originating site requirements for telehealth services to allow qualified staff to furnish kidney disease patient education services via telehealth to a beneficiary regardless of where the beneficiary is geographically located such that kidney disease patient education services could be furnished via telehealth regardless of the beneficiary's location, including at a site not specified in § 410.78(b)(3) of our regulations. We further sought comment on our proposal to waive the originating site facility fee requirements such that CMS would not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations.

The following is a summary of the comments received on our proposed definitions of ''qualified staff'' and ''clinical staff,'' as well as our proposal to waive certain requirements for furnishing kidney disease patient education services such that they can be furnished via telehealth, and our responses.

Comment: A few commenters expressed support for the proposed definitions of ''clinical staff'' and ''qualified staff.'' One such commenter reasoned that these definitions would provide clarity on which clinicians are authorized to furnish kidney disease patient education services pursuant to the waivers implemented in the ETC Model.

Response: We agree that the proposed definitions of ''clinical staff'' and ''qualified staff'' add clarity regarding the types of staff authorized to furnish kidney disease patient education services under the ETC Model waivers implemented in § 512.397(b) of our regulations.

Comment: Many commenters expressed support for the use of telehealth in general, noting that telehealth is particularly good for kidney patients, especially kidney patients who live in rural areas or otherwise face barriers to accessing care. In addition, many commenters expressed support for the specific telehealth waiver in the CY 2022 ESRD PPS proposed rule. Two such commenters reasoned that the proposed telehealth waiver would materially increase attributed beneficiaries' access to kidney disease patient education services. A few commenters who expressed support reasoned that the proposed telehealth waiver would address some barriers to access such services for attributed beneficiaries, such as lack of reliable transportation, lack of childcare, inability to take time away from work, and other socioeconomic barriers, and would afford attributed beneficiaries the choice to receive kidney disease patient education services in a location of their choice. Several commenters referenced the positive experience with and benefits of increased access to telehealth during the PHE. A few commenters expressed support for the proposed telehealth waiver because they believed it would increase the utilization of kidney disease patient education services, which they deem an important benefit.

One commenter expressed support for the proposed telehealth waiver because they believe it will both allow more beneficiaries to receive kidney disease patient education services and advance health equity. Another commenter expressed support for the proposed telehealth waiver because they believe it would help address the challenge of increasing rates of kidney disease in rural areas.

Response: We appreciate the comments and support. We agree with the reasons cited by commenters in support of telehealth generally and the proposed telehealth waiver specifically. However, because the COVID–19 PHE and the section 1135(b)(8) waiver of geographic and site of service restrictions for telehealth originating sites in section 1834(m)(4)(C) of the Act are still ongoing, as described in greater detail below, we are modifying our proposal such that the proposed ETC telehealth waiver policy will apply beginning upon the expiration of the COVID–19 PHE, rather than beginning in MY3 as proposed.

Comment: One commenter expressed support for CMS's proposal to waive the requirements in Section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) so that CMS does not pay an originating site facility fee for kidney disease patient education services furnished via telehealth at a site not specified in § 410.78(b)(3) of our regulations.

Response: We appreciate the commenter's support.

Comment: One commenter expressed opposition to CMS's proposal to waive the originating site fee when telehealth services are offered under the ETC Model's telehealth waiver for kidney disease patient education services furnished via telehealth at a site not specified in § 410.78(b)(3) of our regulations. The commenter stated that the originating site fee was not waived for telehealth services furnished under the section 1135(b)(8) telehealth waiver in effect during the COVID PHE. The commenter also stated that the inclusion of the originating site fee provides an incentive for ETC Participants to offer kidney disease patient education services via telehealth to a broader population. The commenter further noted that, consistent with the proposed incentives to increase access to alternative renal replacement modalities for dual-eligible and LIS-eligible beneficiaries under the ETC Model, allowing ETC Participants to receive the originating site fee for services furnished under the Model's telehealth waivers could assist in increasing access to kidney disease patient education services for dual-eligible and LIS-eligible beneficiaries.

Response: While we appreciate the comment, we respectfully disagree.

First, to clarify, CMS did not propose to waive the originating site fee altogether when telehealth services are offered under the ETC Model's telehealth waiver for kidney disease patient education services. That is, CMS will still pay the originating site facility fee when kidney disease patient education services are furnished via telehealth at a site specified in § 410.78(b)(3) of our regulations. This is true even if the originating site is located in a geographic area not described in § 410.78(b)(4) of our regulations, as we have waived the geographic requirements in § 410.78(b)(4) for purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with this section, regardless of the location of the beneficiary or qualified staff.

Second, while our proposal to implement a telehealth waiver under the ETC Model was informed by the section 1135(b)(8) telehealth waiver in effect during the COVID PHE, our proposed waiver was designed specifically for purposes of the ETC Model. We do not believe it is appropriate, under the ETC Model, for CMS to pay an originating site facility fee to an ETC Participant when an ETC Participant furnishes kidney disease patient education services to a beneficiary via telehealth at a site not specified in § 410.78(b)(3) of our regulations. We anticipate that when an ETC Participant is furnishing kidney disease patient education services to a beneficiary via telehealth at an originating site not specified in § 410.78(b)(3), the site will be the home of a beneficiary, or caregiver, family member, or friend of the beneficiary, or otherwise at a site not maintained by the ETC Participant. We believe this because, relative to many other Medicare services, renal replacement therapy (in particular home dialysis) require the involvement of a caregiver and other family and friends for support, both directly in assisting the beneficiary in learning how to perform home dialysis, and indirectly in preparing a beneficiary's residence for home dialysis (such as ensuring that there is adequate space available for equipment).

When an ETC Participant is furnishing kidney disease patient education services to a beneficiary via telehealth at an originating site not specified in § 410.78(b)(3), the ETC Participant is generally not providing administrative, clinical support, or overhead for the site where the beneficiary is located. Not paying an originating site facility fee under these circumstances is consistent with Medicare payment policy generally, as CMS does not pay an originating site facility fee for telehealth services furnished at an originating site that is the home of an individual.

While CMS does pay the originating site facility fee if the originating site is a patient's home that has been made provider-based to a hospital during the COVID–19 PHE, such a site is not technically considered the patient's home. Additionally, this policy was adopted in recognition of the changes in practice patterns adopted during the PHE for infection control purposes. CMS clarified that, during the COVID–PHE, if applicable requirements are met, a patient's home may be considered a provider-based department of a hospital (HOPD) in recognition that when a physician or other practitioner who ordinarily practices in the HOPD furnishes a telehealth service to a patient who is located in the home, the hospital would often still provide some administrative and technical support for the service (85 FR 27565). We do not believe this policy is appropriate for the ETC Model, as the ETC Model's telehealth waiver will not become effective until the COVID–19 PHE expires, as described elsewhere in this final rule.

Third, for calendar year 2021, the payment amount for the originating site facility fee is 80% of $27.02, or $21.62. It is possible (and indeed, we hope that) the telehealth waiver will increase clinically appropriate furnishing of kidney disease patient education services. We are concerned that paying the originating site facility fee for services furnished via telehealth at an originating site not specified in § 410.78(b)(3) would likely represent too large an impact on the ETC Model's savings estimates, potentially jeopardizing our ability to continue to test the model. In addition, we are concerned that permitting the originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations would increase the 20 percent coinsurance owed by a beneficiary when not reduced or waived by an ETC Participant pursuant to § 512.390(c). The increased coinsurance obligation may dissuade a beneficiary from accessing this important service.

For these reasons, we are finalizing our proposed waiver of the requirement in section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) such that CMS will not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations.

Comment: One commenter expressed support for CMS's proposal to not waive the requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an ''interactive telecommunications system,'' as that term is defined in § 410.78(a)(3) to mean multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Response: We agree that it is appropriate to continue to require that kidney disease patient education services furnished via telehealth be provided through an interactive telecommunications system, such that audio-only telehealth services are not permitted. We are concerned that audio-only kidney disease patient education services would not be effective in meaningfully educating beneficiaries on kidney disease given the complexity of the subject matter. We believe it is important that telehealth kidney disease patient education services include, or at least have the opportunity to include, images, demonstrations, and other visual cues to most effectively accomplish the objectives of kidney disease patient education services.

Comment: A few commenters expressed concern regarding our proposal to not waive the requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an interactive telecommunications system, and recommended that CMS allow the provision of audio-only telehealth services for kidney disease patient education services. Two such commenters reasoned that not every beneficiary has access to interactive telecommunications systems, and one of whom further suggested that requiring the use of video systems would preclude those beneficiaries who may most need access to kidney disease patient education services from benefiting from the proposed telehealth waiver.

The same commenter additionally suggested that CMS should give ETC Participants the opportunity to determine how many beneficiaries would take advantage of audio-only kidney disease patient education services sessions to allow CMS to determine whether such services would represent an effective method of providing beneficiary education. Another commenter suggested that allowing audio-only telehealth services

for kidney disease patient education services would align with other proposed changes to the ETC Model, which, the commenter points out, include a significant focus on health equity.

Response: We do not believe waiving the requirement that telehealth services be furnished via an interactive telecommunications system is necessary to test the ETC Model, either Model-wide or on an ETC Participant-specific basis. We believe that the telehealth waiver, as proposed, will accomplish the goal of increasing access to kidney disease patient education services, and we are interested in learning whether this goal is realized through this particular proposed waiver. While we share the concerns raised by commenters that not every beneficiary has access to an interactive telecommunications system, we are also concerned that audio-only kidney disease patient education services would not be effective in meaningfully educating beneficiaries on kidney disease. As such, we do not agree, at this time, that allowing audio-only telehealth services for kidney disease patient education services would align with CMS's focus on health equity insofar as such a policy may result in beneficiaries of lesser means systematically receiving lower quality kidney education. However, CMS will monitor the extent to which there are barriers in access to interactive telecommunciations systems among attributed beneficiaries. Based on our experience testing this telehealth waiver in the ETC Model, we may consider waiving the requirement that telehealth services be furnished via an interactive telehealth communications system, or other waivers or initiatives necessary to mitigate or eliminate barriers to accessing interactive telehealth communications systems, at a later time, either as part of the ETC Model test or in another initiative.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.397(b)(5) to waive geographic and site of service originating site requirements in section 1834(m)(4)(B) and 1834(m)(4)(C) of the Act and § 410.78(b)(3) and (4) of our regulations for the purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with § 512.397, regardless of the location of the beneficiary or qualified staff, and the requirement in section 1834(m)(2)(B) of the Act and § 414.65(b) of our regulations that CMS pay a facility fee to the originating site with respect to telehealth services furnished to a beneficiary in accordance with § 512.397 at an originating site that is not one of the locations specified in § 410.78(b)(3), with modification. Specifically, we are modifying our proposed regulatory text at § 512.397(b)(5) to change the date on which these waivers become effective. We are modifying both instances of the phrase, ''Beginning January 1, 2022,'' proposed in § 512.397(b)(5) to the phrase ''Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID–19 pandemic[.]''

(2) Kidney Disease Patient Education Services Beneficiary Coinsurance Waiver

Available data and scholarly research suggest that there is a significant relationship between socioeconomic status and prevalence of CKD. For example, evidence suggests that CKD is more prevalent among individuals with lower income.[276] In addition, at least one study suggests that as an individual's CKD severity increases (for example, from CKD III to CKD IV), the likelihood of the CKD patient falling into poverty increases.[277] In light of this research, we stated in the CY 2022 ESRD PPS proposed rule that CMS believes that cost represents a meaningful barrier for beneficiaries in accessing kidney disease patient education services (86 FR 36393). While we also stated that there does not appear to be any research that explicitly investigates to what extent cost barriers preclude access to kidney disease patient education services, the identified relationship between household income or poverty status and prevalence of CKD suggests that cost is an important factor when considering a beneficiary's access to kidney disease patient education services.

Under section 1833 of the Act, the amounts paid by Medicare for kidney disease patient education services are equal to 80 percent of the applicable payment amount; beneficiaries are thus subject to a 20 percent coinsurance for kidney disease patient education services. Kidney disease patient education services can be billed under G0420 for an individual session, or under G0421 for a group session. The current national unadjusted payment for G0420 under the CY 2021 Physician Fee Schedule is $114.10; for G0421, it is $27.22. As such, a beneficiary would be required to pay $22.82 for an individual session of kidney disease patient education services or $5.44 for kidney disease patient education services furnished to a group, which may be higher or lower depending on certain factors, such as the geographic location of the beneficiary. Medicare covers up to six kidney disease patient education services for an individual beneficiary during that beneficiary's lifetime, meaning that a beneficiary may be required to pay $136.92 if six individual kidney disease patient education services are clinically appropriate for that beneficiary, or $32.64 if six group kidney disease patient education services are clinically appropriate for that beneficiary.

In the CY 2022 ESRD PPS proposed rule, we stated that we believe that it is necessary, for purposes of testing the ETC Model, to permit ETC Participants the flexibility to reduce or waive the 20 percent coinsurance requirement for kidney disease patient education services. We also stated that we believe this patient incentive would increase the provision of kidney disease patient education services to beneficiaries, given the relationship between income or poverty and prevalence of CKD, and the relationship between kidney disease patient education services and progression of CKD. In the CY 2022 ESRD PPS proposed rule, we stated that CMS had determined that, if this proposal were finalized, this CMS-sponsored patient incentive would advance the ETC Model's goal of increasing access to kidney disease patient education services, and to making beneficiaries more aware of their choices in preparing for kidney treatment, including the choice of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis.

Accordingly, we proposed at § 512.397(c) to permit, beginning January 1, 2022, ETC Participants to reduce or waive the beneficiary coinsurance obligations for kidney disease patient education services furnished to an eligible beneficiary who does not have secondary insurance on the date the kidney disease patient education services are furnished if

[276] Table 1.2 in United States Renal Data System, *2020 Annual Report, Chronic Kidney Disease: Chapter 1, CKD in the General Population,* available at *https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population* (indicating that the prevalence of CKD in those above the poverty line is 14.4 percent while the prevalence of CKD in those below the poverty line is 17.4 percent. *See also* McClellan, W.M., et al., *Poverty and Racial Disparities in Kidney Disease: The REGARDS Study, Am. J Nephrol,* 2010, Volume 32, Issue 1, pages 38–46, available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2914392/* (providing data suggesting that lower household income is associated with higher prevalence of CKD).

[277] Morton, R.L, et al., *Impact of CKD on Household Income,* Kidney International Reports, Volume 3, Issue 3, 2018, pages 610–618, available at *https://www.sciencedirect.com/science/article/pii/S2468024917304795?via%3Dihub.*

certain conditions are satisfied. We refer to this patient incentive herein as the ''kidney disease patient education services coinsurance patient incentive.'' We stated in the CY 2022 ESRD PPS proposed rule that we expected to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) would be available to protect cost-sharing support that is furnished in compliance with ETC Model requirements with respect to kidney disease patient education services. We noted that if CMS were to make such a determination, the safe harbor for CMS-sponsored model patient incentives would protect an ETC Participant, as that term is defined at § 512.310, who offers a reduction or waiver of coinsurance for kidney disease patient education services to beneficiaries who are eligible to receive kidney disease patient education services, including those eligible pursuant to the waiver described in § 512.397(b)(2), and who do not have secondary insurance on the date that the kidney disease patient education services were furnished.

We proposed that the kidney disease patient education services coinsurance patient incentive would be available to the ETC Participant for kidney disease patient education services furnished by an individual or entity who is qualified staff. We stated that this proposal would align with the individuals who may furnish kidney disease patient education services under § 512.397(b) of this subpart, which are we replacing in its entirety to standardize certain terms and add clarity, as described in greater detail in the CY 2022 ESRD PPS proposed rule and in section VIII.b.3 of this final rule.

We proposed to limit the kidney disease patient education services coinsurance patient incentive to beneficiaries who do not have secondary insurance, because secondary insurance typically provides cost-sharing support of the type CMS proposed in the CY 2022 ESRD PPS proposed rule. In the CY 2022 ESRD PPS proposed rule, we stated that we also believe that limiting the kidney disease patient education services coinsurance patient incentive to beneficiaries without secondary insurance would better ensure that only beneficiaries who need cost-sharing support would receive it, rather than permitting cost-sharing support for all beneficiaries for whom kidney disease patient education services are clinically appropriate.

We also proposed that the kidney disease patient education services coinsurance patient incentive would be available only for kidney disease patient education services that were furnished in compliance with the applicable provisions of § 410.48 of our regulations, which includes a requirement that a beneficiary obtain a referral from the physician (as defined in section 1861(r)(1) of the Act) managing the beneficiary's kidney condition in order for the beneficiary to be eligible to receive kidney disease patient education services. We proposed to include this requirement because we waived some but not all provisions of § 410.48, and because, as stated in the CY 2022 ESRD PPS proposed rule, we believe that the requirement that the beneficiary receive a referral from their physician is important for ensuring that kidney disease patient education services are furnished only to beneficiaries for whom it is clinically appropriate.

We proposed that such coinsurance support would be permitted for the kidney disease patient education services offered either in-person or via telehealth, and that it would be permitted for both individual sessions and group sessions. However, in the CY 2022 ESRD PPS proposed rule we considered limiting the coinsurance support to kidney disease patient education services that are furnished to an individual beneficiary, rather than allowing the coinsurance support for such services furnished either individually or to a group. We noted that the cost burden on beneficiaries who receive kidney disease patient education services in a group setting is much lower than it is on beneficiaries who receive kidney disease patient education services individually. However, as we stated in the CY 2022 ESRD PPS proposed rule, we are concerned that any cost barrier to kidney disease patient education services, even if low, represents a meaningful barrier to some beneficiaries who would otherwise elect to receive such services. We solicited comments on this issue.

We proposed that an ETC Participant that offers coinsurance support for kidney disease patient education services would be required to maintain records of certain information. Specifically, we proposed that an ETC Participant that offers the kidney disease patient education services coinsurance patient incentive would be required to maintain records of the following: The identity of the qualified staff who furnished the kidney disease patient education services for which the coinsurance was reduced or waived; the date the kidney disease patient education services coinsurance patient incentive was provided; the identity of the beneficiary to whom the kidney disease patient education services coinsurance patient incentive was provided; evidence that the beneficiary who received the kidney disease patient education services coinsurance patient incentive was eligible to receive the kidney disease patient education services and did not have secondary insurance; and the amount of the kidney disease patient education services coinsurance patient incentive reduced or waived by the ETC Participant. We proposed to require an ETC Participant that offers this kidney disease patient education services coinsurance patient incentive to maintain and provide the government with access to these records in accordance with 42 CFR 512.135(b) and (c).

We further proposed in proposed 42 CFR 512.160(b)(6)(ii) that, for the ETC Model only, CMS could suspend or terminate the ability of an ETC Participant to offer the kidney disease patient education services coinsurance patient incentive if CMS determined that any grounds for remedial action exist pursuant to § 512.160(a).

We stated in the CY 2022 ESRD PPS proposed rule that, in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS may determine that the anti-kickback statute safe harbor CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the reduction or waiver of coinsurance for kidney disease patient education services permitted under the ETC Model final rule, if issued. We stated in the CY 2022 ESRD PPS proposed rule that we expect to determine that the CMS-sponsored model safe harbor will be available to protect the reduction or waiver of coinsurance that satisfies the requirements of such safe harbor and the provisions of proposed § 512.397(c)(1). We proposed that, if we make this determination, we would specify in regulation text at § 512.397(c)(4) that the safe harbor is available.

We also considered, in the CY 2022 ESRD PPS proposed rule, prohibiting on an ESRD facility or other entity from providing qualified staff or the ETC Participant with financial support to enable such qualified staff or ETC Participant to provide the kidney disease patient education services coinsurance patient incentive. As we stated in the CY 2022 ESRD PPS proposed rule, CMS is concerned that permitting such financial support may encourage unlawful or abusive

arrangements designed to induce or reward referrals for Federal health care program business. We solicited comments on whether this prohibition is necessary to safeguard against fraud and abuse or if other laws effectively provide sufficient protection.

We also considered waiving Medicare payment requirements such that CMS would pay the full amount of the kidney disease patient education services furnished to a beneficiary who does not have secondary insurance, rather than just 80 percent of the amount. 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 respect to testing models described in section 1115A(b) of the Act. As we stated in the CY 2022 ESRD PPS proposed rule, this is the authority under which we would waive such Medicare payment requirements. We stated that, under such a policy, Medicare would pay 100 percent of the payment amount for kidney disease patient education services furnished by Managing Clinicians who are ETC Participants to beneficiaries who do not have secondary insurance, and such beneficiaries would have no cost-sharing obligation for that benefit. However, in the CY 2022 ESRD PPS proposed rule, we determined that this policy would likely represent too large an impact to the ETC Model's savings estimates, and thus would potentially jeopardize our ability to continue to test the ETC Model, if such a policy were finalized.

Given the proposed policies related to programmatic waivers and additional flexibilities available under the ETC Model, we proposed to modify the title of § 512.397 from ''ETC Model Medicare program waivers'' to ''ETC Model Medicare program waivers and additional flexibilities.'' We proposed this change so that the section title would more accurately reflect the contents of the section if our proposed kidney disease patient education services coinsurance patient incentive is finalized.

We solicited public comments on our proposal to allow qualified staff, as we proposed to define the term under § 512.310, to offer coinsurance support for kidney disease patient education services to beneficiaries who are eligible for such services, including those eligible under § 512.397(b)(2), and who do not have secondary insurance on the date the kidney disease patient education services are furnished. We also solicited comment on our proposal to require the ETC Participant to maintain and provide the government with access to records regarding the use of the kidney disease patient education services coinsurance patient incentive.

The following is a summary of the comments received on our proposal to allow qualified staff to offer coinsurance support for kidney disease patient education services to beneficiaries who do not have secondary insurance and our responses.

Comment: Many commenters expressed that cost is a barrier for at least some beneficiaries in accessing kidney disease patient education services.

We also received many comments expressing support for our proposal to allow an ETC Participant to reduce or waive a beneficiary's coinsurance for kidney disease patient education services furnished by qualified staff, in accordance with § 512.397(b)(1), under the ETC Model. One commenter expressed support for the proposal noting that many kidney patients have limited resources, and may choose to forgo education to dedicate such resources to obtaining medications and medical care. Another commenter similarly expressed support because they believe the proposed coinsurance patient incentive would increase access to kidney disease patient education services by removing cost barriers. Yet another commenter expressed support for the proposal, noting that coinsurance payments can burden beneficiaries, particularly those in the most underserved communities. The same commenter also expressed a belief that the proposal will advance the ETC Model's goal of increasing access to kidney disease patient education services, and of making beneficiaries more aware of their choices in preparing for kidney treatment, including the choice to receive home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis.

Response: We agree with the reasons the commenters provided for their support, which is why we proposed and are now finalizing a policy allowing an ETC Participant to reduce or waive a beneficiary's coinsurance for kidney disease patient education services furnished by qualified staff, in accordance with § 512.397(b)(1), under the ETC Model.

Comment: A few commenters expressed opposition to our proposal to limit the proposed coinsurance patient incentive to beneficiaries without secondary insurance. One such commenter expressed that offering the coinsurance patient incentive to more beneficiaries would improve uptake of kidney disease patient education services, which is important given both the historically low percentage of eligible beneficiaries who have been provided kidney disease patient education services, and the important of pre-dialysis education to help beneficiaries make informed treatment decisions. Another commenter stated that, unless CMS can guarantee that Medicaid would cover the coinsurance amount for dually-eligible beneficiaries, the coinsurance patient incentive should be broadened to cover dual-eligible and LIS-eligible beneficiaries, reasoning that such a proposal would ensure these groups' access to appropriate education.

Response: We proposed to restrict the coinsurance patient incentive to only those beneficiaries without secondary insurance because secondary insurance typically covers this type of cost sharing. That is, providing cost sharing support would be redundant for beneficiaries with secondary coverage. Because a beneficiary's secondary insurance will likely cover cost sharing for kidney disease patient education services, we believe our proposed policy would generally succeed in increasing access to beneficiaries by removing cost barriers for those who are obligated to pay cost sharing because it is not covered by their insurance. However, the commenter who expressed concern that Medicaid may not necessarily provide cost-sharing support for kidney disease patient education services raises an important point.

Medicaid will not necessarily cover the coinsurance amount for dual-eligible beneficiaries' kidney disease patient education services, because not all Medicare Savings Programs cover Medicare coinsurance and Medicaid coverage of cost sharing generally varies by State. In some states, Medicaid would cover the cost sharing for kidney disease patient education services, while in other states it would not. In light of this State variation, and to further our stated goal of providing cost sharing support to beneficiaries who are obligated to pay cost sharing because it is not covered by their insurance, we are finalizing a policy that restricts the coinsurance patient incentive to only those beneficiaries without secondary insurance that provides cost sharing support for kidney disease patient education services.

Comment: Two commenters suggested that CMS include both individual and group kidney disease patient education services sessions in the coinsurance patient incentive. One such commenter

reasoned that, while group kidney disease patient education services sessions have minimal costs, even nominal costs can quickly add up for beneficiaries with a chronic condition, especially for beneficiaries with kidney disease, who often see multiple providers and fill multiple prescriptions each month.

Response: We agree with the commenters that, even if the coinsurance amount for group kidney disease patient education services sessions is minimal, these costs can indeed present meaningful barriers to some beneficiaries, including the beneficiaries with multiple chronic conditions and beneficiaries with kidney disease. In light of these comments, we are finalizing our proposed kidney disease patient education services coinsurance patient incentive policy to permit cost sharing support for individual or group kidney disease patient education services sessions alike.

Comment: A few commenters requested clarification relating to our statement in the CY 2022 ESRD PPS proposed rule that we are considering prohibiting an ESRD facility or other entity from providing the ETC Participant with qualified staff or financial support that the ETC Participant would use in furnishing kidney disease patient education services and the proposed cost sharing support. Two such commenters requested clarification specifically on whether ESRD facilities or other entities could enter into arrangements with ETC Participants to provide certain services at fair market value, and proposed that CMS permit such arrangements so long as the services were indeed provided at fair market value. These commenters reasoned that ESRD facilities sometimes provide physician practices with clinical staff under a personal services or other similar arrangement that complies with the Anti-Kickback Statute, the physician self-referral law, and other requirements. The commenters noted that such arrangements often occur when the dialysis facility maintains staff with pertinent expertise, such as expertise with educating patients about chronic kidney disease. These comments expressed a belief that a dialysis facility providing staffing at fair market value would not constitute providing ''financial support'' as CMS expressed concern about in the CY 2022 ESRD PPS proposed rule, so long as the arrangement complies with all applicable fraud and abuse requirements.

Another commenter asserted that the CY 2022 ESRD PPS proposed rule did not clarify whether CMS is considering prohibiting ESRD facilities from providing qualified staff to ETC Participants without compensation, or whether CMS is considering prohibiting dialysis facilities from entering into a payment contract with ETC Participants to provide such services. The commenter expressed the belief that providing staff without compensation would be inappropriate and inconsistent with current fraud and abuse laws, but suggested that a prohibition on contractual payment arrangements between dialysis facilities and ETC Participants for the purpose of providing qualified staff to deliver kidney disease patient education services runs counter to CMS's goals in proposing the kidney disease patient education services coinsurance patient incentive. The commenter expressed the belief that current fraud and abuse rules, combined with the requirements CMS currently imposes relating to kidney disease patient education services, offer sufficient protection against potentially problematic arrangements.

Response: We thank the commenters for their feedback and information. We understand that ESRD facilities and other entities sometimes enter into arrangements with clinicians or other parties to provide certain services. We recognize that some ETC Participants may wish to furnish kidney disease patient education services using staff or other resources furnished under a contractual arrangement with an ESRD facility or other entity. We are concerned, however, that even if such arrangements are structured to comply with all applicable fraud and abuse laws, they could nevertheless result in program abuse. Specifically, such arrangements could operate to circumvent the statutory prohibition against dialysis facilities furnishing kidney disease patient education services. For example, the staff or resources furnished to the ETC Participant from an ESRD facility or related entity could be used to market a specific ESRD facility or chain of ESRD facilities to beneficiaries who may need to choose a dialysis facility in the future.

We do not believe ETC Participants should obtain safe harbor protection for the reduction or waiver of cost-sharing on kidney disease patient education services if such services were furnished by personnel leased from an ESRD facility or related entity. Accordingly, we are adding a provision at § 512.397(c)(1)(ii) to require that the qualified staff furnishing the kidney disease patient education services for which an ETC Participant reduces or waives cost sharing must not be leased from or otherwise provided by an ESRD facility or related entity. For purposes of this provision, a related entity would include any entity that is directly or indirectly owned in whole or in part by an ESRD facility. We believe this aligns with the statutory intent to prohibit ESRD facilities from furnishing kidney disease patient education services.

Comment: Two commenters advocated that CMS should prohibit ESRD facilities from effectively making up the financial difference an ETC Participant would experience by waiving or reducing a beneficiary's coinsurance amount for kidney disease patient education services. One commenter recommended that CMS not finalize a prohibition on an ESRD facility or other entity from providing financial support to enable ETC Participants to reduce or eliminate cost sharing for kidney disease patient education services. This commenter believed that such financial support arrangements should be permitted as long as they comply with all applicable law.

Response: We agree that ESRD facilities should not be permitted to pay ETC Participants in an effort to offset the financial impact of the ETC Participant's lost cost-sharing revenues. We question whether the receipt of any such remuneration could comply with applicable fraud and abuse laws. Such arrangements, including those in which an entity other than an ESRD facility reimburses the ETC Participant for lost cost-sharing revenues, could result in inappropriate referrals of Federal health care program business, patient steering, corruption of medical judgment, and other abuses. Indeed, the receipt of any such remuneration could implicate and potentially violate the Federal Anti-Kickback statute (42 U.S.C. 1320a–7b(b)), and by extension the False Claims Act (31 U.S.C. 3729–3733 and 42 U.S.C. 1320a–7b(g)).

Moreover, we do not believe that permitting such arrangements is necessary to test the model. We are testing a narrowly-tailored exception to the usual prohibition against the reduction or waiver of beneficiary cost-sharing obligations. Permitting any individual or entity other than the ETC Participant to finance cost-sharing support is beyond the scope of the policy we are testing. Accordingly, we are persuaded that safe harbor protection for cost-sharing support furnished by ETC Participants to beneficiaries for kidney disease patient education services should be contingent

on the ETC Participant bearing the full cost of the copayment reduction or waiver. That is, the copayment reduction or waiver may not be financed by a third party, including but not limited to an ESRD facility or related entity. Therefore, we are finalizing at § 512.397(c)(1)(v) a new safeguard that requires the ETC Participant to bear the full cost of any cost-sharing reduction or waiver for kidney disease patient education services.

We note that we did not propose and are not finalizing any provision that would offer safe harbor protection for any arrangement between an ETC Participant and an ESRD facility or other entity. Under this final rule, the only arrangements that may qualify for protection under the safe harbor for CMS-sponsored model patient incentives are arrangements between the ETC Participant and the beneficiary for whom the ETC Participant reduced or waived the kidney disease patient education services coinsurance amount, provided that the arrangements comply with the requirements of the safe harbor as set forth at 42 CFR 1001.952(ii)(2) and the provisions of 512.397(c)(1).

Comment: Several commenters, including some commenters who expressed support for CMS's proposed coinsurance patient incentive policy, suggested that CMS instead waive Medicare payment requirements such that CMS would pay the full amount of the kidney disease patient education services furnished to a beneficiary who does not have secondary insurance, rather than just 80 percent of the amount. One such commenter expressed concern that ETC Participants will not have the financial resources to forgo all or a portion of a beneficiary's coinsurance and will therefore be unable to use the flexibility afforded under this patient incentive to reduce the financial burden of beneficiaries. Two such commenters expressed concern that while waiving coinsurance would serve to increase beneficiary use of kidney disease patient education services, ETC Participants and their qualified staff may lack willingness to provide kidney disease patient education services at a rate that, according to the commenters, would not adequately cover their costs, and that this would diminish the availability of kidney disease education to beneficiaries. Further, these commenters suggested that CMS providing the full payment amount for kidney disease patient education services would alleviate CMS's stated concern that the proposed coinsurance patient incentive could incentivize improper financial assistance from ESRD facilities and other entities. These commenters suggested that, to counterbalance CMS's stated concern that such payment waivers would result in additional Medicare costs under the ETC Model, CMS could exclude the 20 percent coinsurance amounts that CMS would cover under this alternative proposal from ETC cost calculations during the ETC Model period to determine whether this limited additional investment results in improved beneficiary quality of care and an overall cost of care reduction. Two commenters stated that CMS should pay the full amount of the kidney disease patient education services furnished to a beneficiary who does not have secondary insurance because, according to the commenters, the requirements needed to qualify for the coinsurance patient incentive are overly onerous and may present an additional barrier to access to kidney disease patient education services.

Response: We considered this alternative policy in the CY 2022 ESRD PPS proposed rule, but concluded that it would represent too large an impact to the ETC Model's potential savings (86 FR 36394–36395). We believe that the policy we are finalizing, wherein an ETC Participant may reduce or waive cost sharing for kidney disease patient education services, strikes the appropriate balance in providing a new tool for ETC Participants to engage beneficiaries while also helping support the success of the Model. While a policy under which Medicare pays the full amount of the kidney disease patient education services amount, rather than 80 percent of the amount, may result in the highest number of beneficiaries receiving kidney disease patient education services, we believe that the kidney disease patient education services coinsurance patient incentive will result in more beneficiaries receiving kidney disease patient education services compared to the status quo, and will do so without detracting from the savings estimates of the ETC Model.

Moreover, we disagree with the commenters who suggested that CMS could exclude the 20 percent coinsurance payment paid by CMS from the Model's cost calculations. We cannot exclude the 20 percent coinsurance payment paid by CMS from the Model's cost calculations. If we implemented the payment waiver as recommended by the commenters, CMS would need to account for these costs when determining the Model's overall impact on Medicare program expenditures. However, CMS may consider implementing a payment waiver like the alternative we considered in the CY 2022 ESRD PPS proposed rule in a future model or initiative to determine whether such an investment results in improved beneficiary quality of care and an overall cost of care reduction.

Finally, we understand the commenters' concern that the proposed kidney disease patient education services coinsurance patient incentive imposes an administrative burden on ETC Participants who choose to furnish the patient incentive, but we believe that the benefits of reducing cost barriers to kidney disease patient education services through furnishing the kidney disease patient education services coinsurance patient incentive will outweigh this administrative burden. Commenters have expressed that beneficiaries who undergo kidney disease education are more likely to choose home dialysis, and to the extent this is the case, an ETC Participant that furnishes the coinsurance patient incentive might recover the direct and indirect (administrative) costs associated with cost-sharing waivers for such services if the ETC Participant qualifies for a positive PPA. In addition, while we agree that the alternative policy considered in the CY 2022 ESRD PPS proposed rule would alleviate the fraud and abuse concerns we articulated in that rule, we have concluded that existing law and the safeguards finalized in this rule provide sufficient protection against such fraud and abuse.

Final Rule Action: After considering public comments, we are finalizing with modification our proposal to add § 512.397(c) regarding an ETC Participant's ability to reduce or waive the 20 percent coinsurance obligation for kidney disease patient education services. Specifically, we are adding § 512.390(c)(1), which permits ETC Participants to reduce or waive beneficiary cost sharing for kidney disease patient education services furnished on or after January 1, 2022 if the following conditions are satisfied: (i) The individual or entity that furnished the kidney disease patient education services is qualified staff; (ii) the qualified staff are not leased from or otherwise provided by an ESRD facility or related entity; (iii) the kidney disease patient education services were furnished to a beneficiary described in § 410.48(b) or § 512.397(b)(2) who did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished; (iv) the kidney disease patient education services were furnished in compliance with the applicable provisions of § 410.48 and § 512.397(b); and (v) the

ETC Participant bears the full cost of the waiver or reduction of the 20 percent coinsurance requirement under section 1833 of the Act and such reduction or waiver is not financed by a third party, including but not limited to an ESRD facility or related entity.

Under new § 512.397(c)(2), we are finalizing with modification our proposed requirements regarding documentation retention and government access to records regarding the reduction or waiver of beneficiary cost-sharing obligations for kidney disease patient education services furnished under the ETC model. Specifically, we are modifying § 512.397(c)(2)(iii) to read, ''Evidence that the beneficiary who received the kidney disease patient education services coinsurance waiver was eligible to receive the kidney disease patient education services under the ETC Model and did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished.''

Lastly, we are finalizing without change our proposal to include at § 512.397(c)(3) a provision stating that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives is available to protect kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and the conditions set forth in § 512.397(c)(1).

(3) Revising Language Providing Other ETC Model Medicare Program Waivers

We proposed to revise § 512.397(b)(1) through (4) in their entirety to accomplish a few goals (86 FR 36395). First, we proposed to make conforming changes throughout § 512.397(b) to the manner in which CMS discusses kidney disease patient education services. Currently, § 512.397(b) includes references to ''KDE services,'' ''the KDE benefit,'' ''KDE sessions,'' and, simply, ''KDE.'' CMS would change all of these references to ''kidney disease patient education services'' for clarity and to conform with the term used elsewhere in our regulations.

In addition, we proposed to make conforming changes through § 512.397(b) to the manner in which CMS discusses the individuals who are permitted to furnish kidney disease patient education services under the ETC model programmatic waivers. Specifically, as discussed previously, CMS proposed to add definitions for ''clinical staff'' and ''qualified staff'' in the CY 2022 ESRD PPS proposed rule, as CMS believes clarifying how CMS discusses these individuals in § 512.397(b) will enhance clarity. Finally, we proposed to remove the ''clinic/group practice'' from the list of individuals or entities that are permitted to furnished kidney disease patient education services under the ETC Model programmatic waivers, and to remove the waiver of 42 CFR 410.48(c)(2)(i) from § 512.397(b)(1) of this part. We stated in the CY 2022 ESRD PPS proposed rule that we believe that its inclusion of clinic/group practices previously was in error, and we noted that a clinic/group practice is not able to furnish or bill for kidney disease patient education services under existing law and that CMS did not intend for the waiver described in § 512.397(b) to permit anyone other than a clinician to furnish kidney disease patient education services. Because the waiver of the requirements under 42 CFR 410.48(c)(2)(i) was implemented only to broaden the ''qualified person'' that could furnish kidney disease patient education services pursuant to § 512.397(b)(1) to include a clinic/group practice, we proposed to remove references to 42 CFR 410.48(c)(2)(i) in § 512.397(b)(1) of this part.

We solicited public comments on these proposed changes to § 512.397(b) to make conforming and clarifying changes to the manner in which CMS discusses kidney disease patient education services and the individuals who are permitted to furnish kidney disease patient education services under the ETC Model waivers described in § 512.397(b), and to our proposed removal of ''clinic/group practice'' from the list of individuals or entities who may, under the ETC Model waivers described in § 512.397(b), furnish kidney disease patient education services.

CMS did not receive any comments regarding the proposed conforming and clarifying changes to § 512.397(b) of our regulations. However, we did receive some comments suggesting that CMS make additional changes to the kidney disease patient education services waivers in § 512.397(b). The following is a summary of those comments and our responses.

Comment: We received a few comments asking CMS to further increase the scope of the kidney disease patient education services waivers, specifically in order to allow additional clinicians and healthcare sites to furnish kidney disease patient education services, including ESRD facilities, home dialysis nurses, and Certified Nephrology Nurses (CNNs).

Response: While we understand the commenters' interest in increasing even further the types of clinicians and entities that may furnish kidney disease patient education services under the ETC Model, we believe that our current policy provides sufficient flexibility to test the Model. Accordingly, we are not updating § 512.397(b) at this time to add additional types of clinicians and entities that may furnish kidney disease patient education services under the Model.

Comment: We received several comments urging CMS not to grant a waiver to allow ESRD facilities to be able to bill for kidney disease patient education services, due to concerns about potential quality of education and the entrenchment of the existing dialysis market structure.

Response: We do not believe that a waiver of the requirement preventing ESRD facilities from billing for kidney disease patient education services is necessary for testing the model. ESRD facilities are already required to provide information to beneficiaries about their treatment modality options in the ESRD facility conditions for coverage at § 494.70(a)(7) and to develop and implement a plan of care that addresses the patient's modality of care, at § 494.90(a)(7), and the costs for doing so are already included in the payment for the ESRD PPS bundled payment. Accordingly, we are not modifying § 512.397(b) to permit ESRD facilities to furnish kidney disease patient education services under the Model at this time.

Comment: We received a few comments expressing concern about the quality of education that beneficiaries receive as part of kidney disease patient education services and urging that CMS create accredited curricula to ensure consistent education.

Response: We appreciate this feedback and are monitoring utilization of kidney disease patient education services to see potential effects on care. We believe that the required content for kidney disease patient education services, as set forth in 42 CFR 410.48(d), shows the minimum of what must be covered but urge interested stakeholders to consider creating a curriculum that could be used by Managing Clinicians and other qualified staff to administer kidney disease patient education services.

Comment: A few commenters suggested that CMS use its waiver authority to authorize referrals for kidney disease patient education services issued by nurse practitioners. Two such commenters also proposed that CMS use its waiver authority to additionally authorize physician assistants and clinical nurse specialists

to issue referrals for kidney disease patient education services.

Response: As required under 42 CFR 410.48(b)(2), Medicare Part B covers kidney disease patient education services only if the beneficiary obtains a referral from the physician managing the beneficiary's kidney condition. We did not consider issuing a waiver to broaden the categories of clinicians who could issue referrals for kidney disease patient education services in the CY 2022 ESRD PPS proposed rule. Moreover, we currently have no evidence to suggest that the waiver suggested by the commenters would be necessary solely for purposes of testing the model, as would be required to issue such a waiver under section 1115A(d)(1) of the Act. In addition, we do not currently have, and no commenter provided, evidence that broadening the categories of clinicians who could issue a referral for kidney disease patient education services would continue to ensure clinical appropriateness. As such, we will continue to require that the physician managing the beneficiary's kidney condition refer a beneficiary for kidney disease patient education services in order for Medicare to pay for such services as required under 42 CFR 410.48(b)(2). However, we will continue to consider the commenters' suggestions, and we may consider broadening the categories of clinicians who may issue a referral for kidney disease patient education services in future rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal to make conforming and clarifying changes to our regulation at § 512.397(b), without modification. After considering public comments, we will not be altering the curriculum for kidney disease patient education services or allowing any additional types of Medicare providers or suppliers to furnish and bill kidney disease patient education services beyond clinical staff and qualified staff at this time.

C. Requests for Information on Topics Relevant to the ETC Model

1. Peritoneal Dialysis Catheter Placement—Request for Information (RFI)

Through the CY 2022 ESRD PPS proposed rule (86 FR 36395), we sought input on how we can test and use Medicare payment policy, under the ETC Model, to promote placement of PD catheters. Specifically, we sought feedback on the following questions:

a. What are the key barriers to increased placement of PD catheters?

b. How can CMS promote placement of PD catheters in a more timely manner?

c. Should the Innovation Center use its authority to test alternative payment structures to address the barriers to PD catheter placement as a part of the ETC Model? If so, why and how?

For the complete discussion of this RFI, see the CY 2022 ESRD PPS proposed rule, 86 FR 39395 through 39396.

Comments: Commenters expressed general concern that CMS continues to address barriers to home dialysis one provider type at a time rather than holistically as an extended series of barriers and decision points that patients face beginning when they are in earlier stages of kidney disease.

Most commenters agreed with the main barriers to PD catheter placement described in the RFI, including the lack of availability of hospital-based catheter insertion teams to perform PD catheter placements, lack of appropriate operating room time, and a lack of training on PD catheter placement for vascular surgeons. But the commenters suggested additional barriers for CMS's consideration.

First, commenters noted that the COVID–19 pandemic has limited the ability of health care providers to perform elective procedures on a timely basis. According to the commenters, hospital operating rooms effectively halted PD catheter implantation in many hospitals for several months. Rural facilities were particularly hit because these communities rely on surgeons who travel in from larger communities and have limited availability. One commenter noted that incentivizing, or disincentivizing, providers through payment changes or Innovation Center models would not fix the core issue for rural dialysis facilities unless there are enough scheduled patients to make a trip financially feasible. This commenter suggested that as an alternative, CMS should consider methods to reduce the prevalence of ESRD in the long term with a specific focus on rural areas. While this approach may not create immediate savings, reducing the rate of ESRD would significantly benefit CMS in the years to come.

A commenter noted that many of the candidates for prospective PD catheter placement are either not yet eligible for Medicare or are uninsured, and that there is little incentive for hospitals or other facility settings to address the lack of availability of vascular surgeons to perform PD catheter placements, lack of appropriate operating room time, and a lack of training on PD catheter placement for vascular surgeons. Another commenter noted a concern regarding the number of physicians trained to perform PD catheter placement as many of the more experienced PD catheter physician providers are in the later stages of their careers and there are not replacement providers in the pipeline when they retire.

The majority of commenters mentioned the largest barrier for PD catheter placement is low reimbursement, making it difficult to encourage new surgeons and other physicians to become adept at PD catheter implantation. One commenter specifically mentioned that many of the standalone vascular access centers have closed because of the reduction of CMS payments to vascular access surgeons. Unlike the transplant surgeons, who may be incentivized to increase rates of transplantation through increased revenue resulting directly from increasing the number of transplants performed, there are no other direct or indirect incentives for vascular surgeons or vascular access centers to increase rates of, PD catheter placements that can work outside the model to address these concerns. Accordingly, commenters suggested that it would be appropriate to create a separate PD catheter placement incentive under the ETC Model.

As the ETC Model currently seeks to change payment incentives only for ETC Participants (ESRD facilities and Managing Clinicians in Selected Geographic Areas) and, doesn't provide direct incentives for vascular access surgeons to work with ETC Participants, commenters strongly urged CMS to thoughtfully consider to what extent ETC Participants can influence increased rates of PD catheter placement. Despite the importance of dialysis access procedures to patients, commenters noted that ETC Participants currently have little influence on surgeons and hospitals performing dialysis access procedures in a fee-for-service structure. This factor limits the ability of ETC Participants to increase home dialysis utilization, which is contingent on timely and high-quality PD catheter placement. Commenters also urged CMS to consider establishing an incentive payment of at least $360.62 to surgeons and other access specialists in the ETC Model to achieve this goal.

Several commenters suggested that a voluntary track or option could be added to the ETC Model under which ETC Participants would receive a payment increase per PD placement (of at least an additional $360.62 per PD catheter procedure) to equalize the

reimbursement between PD catheter insertion and vascular placement within the Model. A voluntary track would allow participants to opt-in to further test broader and more comprehensive incentive payments. This track would allow for comparison of rates of PD catheter placement within and outside the model, to evaluate whether the payment increase within the Model increased the rate of PD catheter placement. Others didn't think the incentive could be tested in the current model because ETC Participants have no ability to influence the behavior of surgeons or interventionalists who place PD catheters. However, these commenters noted they would be supportive of the incentive in another context.

Several commenters suggested that the Innovation Center should pilot bonus or increased payments for PD catheter placement outside of the ESRD PPS and MCP. These commenters recommended that the Innovation Center consider testing a bonus incentive payment for vascular surgeons, hospitals, and surgical centers that would increase reimbursement for PD catheter placement commensurate with reimbursement provided for AV Fistula reimbursement. According to the commenters, this incentive payment should not be budget neutral to the ESRD PPS or the MCP, but instead should be viewed in the broader context of physician, hospital, and outpatient surgical center reimbursement systems.

Other commenters suggested financial options with less detail. One commenter suggested that CMS can encourage the placement of PD catheters by not only maintaining the reimbursement levels for office based placed catheters but increasing the reimbursement to levels that are on par with Ambulatory Surgery Center settings. Another commenter suggested paying PD catheter placement over time—that is, adding longevity payments so the surgeon gets payments for patients staying on PD at 90 days and 180 days—to align interests across nephrologists and PD providers. Another commenter suggested a bonus payment per diagnostic related group (DRG) of new ESRD dialysis starts in the hospital who are leaving with a PD catheter, including urgent PD. Lastly, another commenter suggested that PD catheter placement be designed as an urgent procedure to be prioritized by the hospital under emergent procedures.

There were also several comments related to use of Innovation Center authority. The first such comment suggested that CMS propose including as ETC Participants those surgeons who bill for dialysis vascular access procedures including PD catheter placement identified based on certain CPT codes (for example, 36818, 36819, 36820, 36821, 36825, 36830, 36831, 36832, 36833, 36838, 49324, 49418, 49421). According to the commenter, including these surgeons in the model would provide an incentive for the surgeons to partner with other providers to ensure the timely placement, repair, and revision of vascular accesses for patients with ESRD. The second such comment had concerns with RVUs in the PFS and suggested the Innovation Center has authority to supplement, beyond the PFS, payments to surgeons that increase access to and availability of procedures that are ''gateways.'' Another such comment urged the Innovation Center to address PD catheter placement and consider possible alternate payment structures such as retroactive payment for successful placement of PD catheters that are proven to have been successful over time or establishment of a bonus structure similar to the Kidney Transplant Bonus under the KCC Model; the commenter also suggested that such innovations should include pediatric patients. The same commenter also urged CMS to not exclude pediatric patients from innovative policies to promote PD catheter placement.

Response: We plan to continue working with other agencies and stakeholders to coordinate and to inform our decisions regarding the potential for incorporating peritoneal dialysis into the ETC Model and any related quality measurement and reporting requirements. While we stated that we would not be responding to specific comments submitted in response to this RFI in the CY 2022 ESRD PPS final rule, we will actively consider all input as we continue testing the ETC Model. Any updates to specific program requirements related to peritoneal dialysis and quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

2. Beneficiary Experience Measure—Request for Information

While a beneficiary experience measure is not currently included in the ETC Model, in the CY 2022 ESRD PPS proposed rule (86 FR 36396), we sought comment on the inclusion of a measure to capture the beneficiary experience of home dialysis care. We invited public comment on any aspect of a patient experience measure. We noted that questions to consider include the following:

a. What domains of a patient experience of care with home dialysis would be the most useful to assess and why?

b. Would you prefer the measure to be newly developed or an update to an existing measure? If an update, which existing measure should be updated?

c. How would a patient experience measure be best used to further the purpose of the ETC Model?

d. How should CMS use a patient experience measure to assess the quality of care of beneficiaries?

e. How should CMS use a patient experience measure to incentivize improved quality of care in the ETC Model and/or for other CMS programs?

CMS also considered publishing the quality outcomes for the ETC Model. We invited public comment on any aspect of reporting quality data, and specifically sought input on the following:

f. What is the frequency with which CMS should disseminate the results?

g. What should be the unit of analysis for the reporting data?

For the complete discussion of this RFI, see the CY 2022 ESRD PPS proposed rule, 86 FR 39396.

Comments: Commenters were appreciative that CMS solicited feedback and there was overwhelming support for inclusion of a measure assessing beneficiary experience on home dialysis in the ETC Model. In general, the commenters thought the inclusion of a measure to assess beneficiary perceptions of the care they receive would be useful to inform changes that can improve the patient's health and well-being. Commenters concurred with CMS that the current ICH CAHPS is not sufficient to capture the beneficiary experience of home dialysis patients and strongly encouraged CMS to work with the kidney community to develop a useful measure that is endorsed by the National Quality Forum (NQF).

A few commenters continued to recommend that CMS continue to develop and improve the ICH CAHPS, with a particular focus on adding a home dialysis survey to allow the patient experience to be compared across settings.

However, more commenters recommended that the agency not update an existing measure, such as ICH CAHPS or the Patient Activation Measure (PAM), and instead develop an entirely new instrument and include questions that are most meaningful to patients. A commenter noted that measuring the patient experience of dialysis in a home setting includes components of in-center dialysis, home

health, and home medical equipment, in addition to topics that are unique to this care setting and patient population. No existing survey touches on all aspects of this distinctive experience. Commenters asked CMS to consider including topics specific to dialysis care at home, such as patient training on equipment, supplies, and safety, and communication with and access to the patient's care team. According to commenters, CMS could convene a Technical Expert Panel (TEP) to develop and test a tool to measure the patient voice in their treatment with home dialysis that would include satisfaction, patient activation, quality of life and economic impact of the treatment at home.

Several commenters commented there are already private-sector efforts to develop a survey tool to measure home dialysis patient experience. Commenters encouraged CMS to work closely with these efforts, and to actively support the psychometric testing and validation necessary to ensure that there is a valid and reliable instrument that can be utilized broadly across providers in assessing the experience of home dialysis patients. Commenters specifically mentioned that any Innovation Center effort should complement and not replicate potential efforts to leverage the Home Dialysis Care Experience (Home-DCE) instrument developed and initially tested by the University of Washington. Commenters further expressed hope that this measure will eventually be tested more broadly and be submitted to NQF for endorsement and use in the CMS ESRD QIP.

Several commenters mentioned that the survey response rate for ICH CAHPS has declined significantly in recent years. Therefore, the commenters recommended that any patient experience measure CMS uses should impose minimal burden on patients and providers. In addition, commenters noted that there is a critical need to develop and implement a patient experience tool that does not further health inequities. Lastly, commenters recommended that any home dialysis patient experience measure CMS implements should be relevant to other CMS programs, such as the ESRD QIP.

Some commenters suggested that a new measure should address the following areas: Ease of use of their modality/device; patient/provider burden in self administration or helping support a loved one; sense of support from the care team.; sense of respect and value from the care team; and communication with the care team. One commenter recommended including three specific questions in a new home dialysis patient experience measure. The first is ''if the patient previously received in-center dialysis, does the patient have better quality of life on home dialysis?'' The second is ''is the patient on home dialysis more able to engage in activities of daily living (ADLs)?'' The final question is ''are dialysis facility staff supportive for patients on home dialysis?''

Some commenters suggested additional mandatory measures in the ETC Model. Commenters suggested an advance care planning measure specifically because it is critical for patients and clinicians to define goals of care. Commenters also suggested measures regarding palliative care access and utilization because there is mounting evidence that ESRD patients who have access to or are enrolled in palliative care programs have better outcomes and have more support for treatment choices. Lastly, commenters suggested a measure specific to timely and appropriate referral to hospice to encourage timely and appropriate referral to hospice. The commenters recommended that this measure should also provide documentation of include evidence of goals of care and advance care planning.

With regard to reporting quality outcomes, commenters supported transparency for beneficiaries attributed to ETC Participants. Commenters suggested that reporting of quality outcomes occur annually in order to be consistent with the ESRD QIP timeline. Commenters also recommended the quality outcomes be available via a website, as well as posted at each facility in the ETC Participant's aggregation group. Specifically, because the ETC Model is focused on aggregation at the HRR level, commenters recommended that the data should be at that aggregated level rather than at the individual ETC Participant level.

Response: We appreciate all the comments and interest in this topic and believe that this input is very valuable in the continuing development of the quality measurement efforts for the ETC Model. We will continue to take all concerns, comments, and suggestions into consideration.

VI. Requests for Information

A. Informing Payment Reform Under the ESRD PPS

Over the last several years, CMS, in conjunction with its contractor, has been conducting research, including holding three technical expert panels (TEPs), to explore possible improvements to the ESRD payment model. Additionally, in the CY 2020 ESRD PPS proposed rule (84 FR 38398 through 38400), CMS invited further comment on a number of topics, including expanding the outlier policy to include composite rate drugs, laboratory tests and supplies; reporting the length of each dialysis session directly on the ESRD claim; patient characteristics which contribute significantly to the cost of dialysis care; and improving the quality of facility-level data as reflected in the Medicare cost report. Stakeholders have asked CMS to explore a refined case-mix adjustment model for the ESRD PPS, stating that the existing case mix adjustors may not correlate well with the current cost of dialysis treatment.

Accordingly, in the CY 2022 ESRD PPS proposed rule (86 FR 36398 through 36409), CMS included a detailed request for information (RFI) on several topics in order to inform payment reform under the ESRD PPS. Those topics included six focal areas: (1) The LVPA payment methodology; (2) calculations for the case-mix adjustment; (3) the calculation for the outlier payment adjustment; (4) the current pediatric dialysis payment model; (5) modifications to the pediatric, the ESRD PPS and the hospital cost report; and (6) payment for home dialysis for Medicare beneficiaries with acute kidney injury. For each topic, we provided background information, reviewed current issues and stakeholder concerns, described suggestions that we received, and included specific requests for information. Although we are not presenting that information again in this final rule, we refer readers to the complete discussion in the CY 2022 ESRD PPS proposed rule, 86 FR 36396 through 36409.

We received numerous public comments in response to our RFI on payment reform under the ESRD PPS, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; an independent commenter; and MedPAC. A high level description of these comments is included below. We will provide more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.*

1. Calculation of the Low-Volume Payment Adjustment (LVPA)

Of the fourteen responses to the LVPA RFI, all commenters supported either eliminating or revising the current LVPA or rural adjustment. One small dialysis organization within a large non-profit health system responded that they are reliant upon the LVPA and the rural adjustment, and support both adjustments, albeit with modifications. Several commenters agreed with MedPAC's suggestion for the low volume and isolated (LVI) adjustment. Several commenters opposed the census tract methodology with some stating that it is complex and lacks transparency.

2. Calculation of the Case-Mix Adjustments

In response to the RFI for current case-mix methodology, several commenters recommended changes or removal of the case-mix adjusters, including refinement of the age and weight (BSA and BMI) adjustments and removal of the comorbidity adjustments, based on declining frequency of claims containing comorbidities. Commenters expressed their belief that the comorbidity categories no longer protect beneficiary access and no longer correlate with increased costs. Numerous commenters expressed support for the current onset of dialysis adjustment. Most commenters did not support the collection of time on machine data on claims or cost reports to allocate composite rate costs. MedPAC recommended that CMS develop a one-equation regression model in place of the current two-equation model currently used as the basis for the ESRD PPS.

3. Calculation of the Outlier Adjustment

In response to the current RFI for the calculation of the outlier payment adjustment, several commenters recommended changes to the outlier policy, expressing concerns about the current outlier policy because it continues to achieve less than the target amount of outlier payments equal to 1.0 percent of total PPS payments. They suggested various strategies for addressing the outlier policy, including reducing the outlier threshold, and excluding TDAPA and TPNIES payments in the outlier calculation methodology. Several commenters supported the use of the FDL trend using historical utilization data. Commenters also recommended the creation of a mechanism to return unpaid outlier amounts to the ESRD PPS.

4. Calculation of the Pediatric Dialysis Payment Adjustment

In the response to RFI for calculation of pediatric dialysis payment adjustment, all the commenters expressed that the total costs of ESRD care delivered to pediatric dialysis patients are not covered by the current ESRD bundled payment and existing pediatric multipliers. Several commenters stated that they did not believe that using duration of treatment is a valid proxy for composite rate costs. Some commenters recommended that a combination of age, weight and pediatric-specific comorbidities be used as a proxy for composite rate costs for pediatric patients. A few commenters recommended streamlining the reporting for claims and cost reports.

5. Modifying the Pediatric Dialysis, ESRD PPS and Hospital Cost Reports

In the responses to RFI for modifying the pediatric cost report, commenters supported updating the pediatric cost report to allow facilities to include costs that cannot be currently reported on the cost report. Specific recommendations included breakdown of patient age groups, pediatric-specific dialysis supplies, additional overhead at hospital outpatient dialysis facilities, psychosocial support, specialized pharmacy needs and costs unique to the pediatric population for home dialysis.

Several commenters noted that, despite best efforts to educate reporting and billing staff, hospitals often triage their cost reporting obligations, focusing on those that affect payment over those that do not; they stated that this is particularly true with pediatric dialysis costs. In order to improve reporting, the commenters recommended streamlining the reporting required and making it more consistent with reporting required from the State Medicaid programs or the private payers.

In the responses to RFI for modifying the ESRD PPS and Hospital Cost Reports, we received input from ten commenters consisting of large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; an independent commenter; and MedPAC. All the commenters expressed support for making improvements to the cost report that will streamline reporting and improve accuracy of information collected that informs payment policy. Additionally, commenters recommended CMS consider modifying hospital cost report reporting instructions to ensure complete, consistent, and accurate data reporting as well as make timely updates to reflect changes to payment policies, including the TDAPA and TPNIES. These commenters cautioned CMS that prior to making changes, CMS should weigh the burden of data collection against the benefit to the system in collecting it.

6. Modifying Site of Services Provided to Medicare Beneficiaries With Acute Kidney Injury (AKI)

The responses to the RFI for modifying site of service provided to Medicare beneficiaries included numerous requests to allow payment for home dialysis for patients with AKI. Of the 16 total comments received on this topic, 15 discussed modification of the site of service requirements, with commenters supporting payment for AKI patients receiving dialysis in home settings, including skilled nursing facilities. Several commenters favored modification of the site of service requirements in concert with payment of home dialysis for AKI patients when deemed appropriate by health care providers.

7. CMS Response to Public Comments

We appreciate the public input and comments on suggested refinements to the ESRD PPS in response to our RFI in the CY 2022 ESRD PPS proposed rule. We will take all of these comments into consideration for possible future rulemaking.

VII. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections

of this document that contain information collection requirements (ICRs):

B. Requirements in Regulation Text

In sections V through V.B of this final rule, we are revising the regulatory text for the ETC Model. However, the changes do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. We stated that the median hourly wage of a Medical Records and Health Information Technician is $21.20 per hour.[278] We also stated that fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimated an hourly labor cost of $42.40 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We stated that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we stated that there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2024 that we discussed in the CY 2021 ESRD QIP final rule (85 FR 71473 through 71474) and to estimate the total information collection burden in the ESRD QIP for PY 2025. We provided the re-estimated information collection burden associated with the PY 2024 ESRD QIP and the newly estimated information collection burden associated with the PY 2025 ESRD QIP in section VII.C.3 of the proposed rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2024 and PY 2025 (OMB Control Numbers 0938–1289 and 0938–1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Although, as noted in section IV.B.2. of the proposed rule, we are now using EQRS to report data that was previously reported in CROWNWeb, the data validation methodology remains the same. Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In the proposed rule, we updated these estimates using a newly available wage estimate of a Medical Records and Health Information Technician. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $31,800 (750 hours × $42.40), or an annual total of approximately $106.00 ($31,800/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be revised in the information collection request (OMB control number 0938–1289).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying our policy to reduce the number of records required from each facility participating in the NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are asked to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $63,600 (1,500 hours × $42.40), or a total of approximately $212 ($63,600/300 facilities) per facility in the sample. While the burden hours estimate will not change, the burden cost updates associated with these requirements will be revised in the information collection request (OMB control number 0938–1340).

3. EQRS Reporting Requirements for PY 2024 and PY 2025 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2021 ESRD PPS final rule, we estimated that the burden associated with CROWNWeb (now

[278] *https://www.bls.gov/oes/current/oes292098.htm.* Accessed on June 7, 2021.

EQRS) reporting requirements for the PY 2024 ESRD QIP was approximately $208 million (85 FR 71400).

As discussed in section IV.C. and section IV.D. of this final rule, we are finalizing our proposed measure suppressions that would apply for PY 2022 and updates to the scoring methodology and payment reductions for the PY 2022 ESRD QIP. In the proposed rule, we also announced an extension of EQRS reporting requirements for facilities due to systems issues. However, we believe that none of the policies finalized in this final rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. We are not finalizing any changes that would affect the burden associated with EQRS reporting requirements for PY 2024 or PY 2025. However, we have re-calculated the burden estimate for PY 2024 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. Consistent with our approach in the CY 2021 ESRD PPS final rule (85 FR 71474), in the proposed rule we estimated that the amount of time required to submit measure data to EQRS was 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this final rule. There are 229 data elements for 532,931 patients across 7,717 facilities. At 2.5 minutes per element, this yields approximately 658.94 hours per facility. Therefore, the PY 2024 burden is 5,085,050 hours (658.94 hours × 7,717 facilities). Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2024 total burden cost is approximately $215 million (5,085,050 hours × $42.40). There is no net incremental burden change from PY 2024 to PY 2025 because we are not changing the reporting requirements for PY 2025.

VIII. Regulatory Impact Analysis

A. Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980; Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 801(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

As required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

This rule finalizes updates to the ESRD PPS for CY 2022, as required by section 1881(b)(14)(F) of the Act. The routine updates include the CY 2022 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2022 for renal dialysis services furnished to ESRD beneficiaries, as required by section 1881(b)(14)(F) of the Act.

b. AKI

This rule also finalizes updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI, as required by section 1834(r) of the Act, as added by section 808(b) of the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) enacted on June 29, 2015. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2022 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

Section 1881(h)(1) of the Act requires a payment reduction of up to 2 percent for eligible dialysis facilities that do not meet or exceed the mTPS established with respect to performance standards for the ESRD QIP each year. This final rule finalizes updates for the ESRD QIP, including the adoption of a measure suppression policy and the suppression of several ESRD QIP measures under that measure suppression policy, updates regarding the scoring methodology and payment reductions for the PY 2022 ESRD QIP, an update to the SHR measure, and an update to the PY 2024 performance standards.

d. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the

Act, which authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This final rule will refine the methodology for setting and updating achievement and improvement benchmarks for participating ESRD facilities and Managing Clinicians serving the ESRD population over the remaining years of the ETC Model, among other changes. As described in detail in section V.B of this final rule, we believe it is necessary to adopt certain changes to the ETC Model. Notwithstanding the changes, we continue to anticipate improvement in quality of care for beneficiaries and reduced expenditures under the ETC Model inasmuch as the Model is designed to create incentives for Managing Clinicians and ESRD facilities to support beneficiaries, along with their families and caregivers, in choosing the optimal kidney replacement modality.

B. Overall Impact

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $290 million in payments to ESRD facilities in CY 2022, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and TPNIES payment.

2. AKI

We estimate that the updates to the AKI payment rate will result in an increase of approximately $1 million in payments to ESRD facilities in CY 2022.

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits for ESRD PPS and AKI

Under the CY 2022 ESRD PPS and AKI payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating ESRD PPS and AKI payments by 1.9 percent based on the final CY 2022 ESRD PPS market basket update less the final CY 2022 productivity adjustment will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this final rule regarding ESRD PPS and AKI rates-setting will create additional cost or burden to ESRD facilities.

b. ESRD QIP

For PY 2024 and PY 2025, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of dialysis facilities. We note that the estimated total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and the estimated number of hours needed to complete data entry for EQRS reporting are the same as they were in the proposed rule. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study), the NHSN validation study, and EQRS reporting. As discussed in section IV.C. and section IV.D. of this final rule, we are finalizing our proposed measure suppressions that would apply for PY 2022 and updates to the scoring methodology and payment reductions for the PY 2022 ESRD QIP. We also announced an extension of EQRS reporting requirements for facilities due to systems issues in the proposed rule. However, we believe that none of the policies finalized in this final rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period.

We also finalized the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $215 million in information collection burden, which includes the cost of complying with this rule, and an additional $17 million in estimated payment reductions across all facilities for PY 2024.

For PY 2025, we estimate that the proposed revisions to the ESRD QIP would result in $215 million in information collection burden, and $17 million in estimated payment reductions across all facilities, for an impact of $232 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule.

c. ETC Model

We estimate that the changes to the ETC Model will increase the Model's projected direct savings from payment adjustments alone by $5 million over the duration of the Model. We estimate that the Model will generate $28 million in direct savings related to payment adjustments over 6.5 years with the adopted changes, and would generate $23 million in savings in the absence of the finalized changes.

3. Transfers for ESRD PPS and AKI

We estimate that the finalized updates to the ESRD PPS and AKI payment rate will result in a total in increase of approximately $290 million in payments to ESRD facilities in CY 2022, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $1 million in payments to ESRD facilities in CY 2022 due to the finalized updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately $230 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $60 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities, which will review

this final rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the May, 2020 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes119111.htm.* Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 300 minutes (5 hours) for the staff to review half of this final rule, which is approximately 75,000 words. For each entity that reviews the rule, the estimated cost is $571.20 (5 hours × $114.24). Therefore, we estimate that the total cost of reviewing this regulation is $163,363.20 ($571.20 × 286).

5. Impact Statement and Table

a. CY 2022 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2021 to estimated payments in CY 2022. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2021 and CY 2022 contain similar inputs.

Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2020 data from the Part A and Part B Common Working Files as of February 12, 2021, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2020 claims to 2021 and 2022 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this final rule. Table 9 shows the impact of the estimated CY 2022 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2021.

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TABLE 9: Impacts of the Changes in Payments to ESRD Facilities for CY 2022[1]

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Effect of 2022 Changes in Outlier Policy (C)	Effect of 2022 Changes in Wage Index (D)	Effect of 2022 Changes in Payment Rate Update (E)	Effect of Total 2022 Final Changes (F)
All Facilities	7,761	44.1	0.6%	0.0%	1.9%	2.5%
Type						
Freestanding	7,381	42.4	0.6%	0.0%	1.9%	2.5%
Hospital based	380	1.7	1.1%	0.0%	2.2%	3.3%
Ownership Type						
Large dialysis organization	5,733	33.0	0.6%	0.0%	1.8%	2.4%
Regional chain	1,167	6.8	0.6%	0.1%	2.1%	2.8%
Independent	475	2.5	0.6%	-0.1%	2.1%	2.6%
Hospital based[2]	380	1.7	1.1%	0.0%	2.2%	3.3%
Unknown	6	0.0	0.6%	-0.4%	1.8%	2.0%
Geographic Location						
Rural	1,276	6.4	0.6%	0.0%	1.9%	2.5%
Urban	6,485	37.8	0.6%	0.0%	1.9%	2.5%
Census Region						
East North Central	1,217	5.8	0.6%	-0.2%	1.9%	2.2%
East South Central	613	3.3	0.8%	-0.4%	1.9%	2.3%
Middle Atlantic	870	5.2	0.7%	-0.2%	2.0%	2.5%
Mountain	431	2.4	0.4%	0.0%	1.9%	2.2%
New England	202	1.3	0.5%	-0.6%	1.9%	1.8%
Pacific[3]	961	6.4	0.4%	0.5%	1.9%	2.8%
Puerto Rico and Virgin Islands	52	0.3	0.5%	-0.7%	1.9%	1.6%
South Atlantic	1,806	10.6	0.6%	0.3%	1.9%	2.8%
West North Central	504	2.3	0.6%	0.0%	1.9%	2.5%
West South Central	1,105	6.6	0.6%	-0.3%	1.9%	2.2%
Facility Size						
Less than 4,000 treatments	1,295	2.0	0.5%	-0.1%	1.9%	2.3%
4,000 to 9,999 treatments	3,158	13.1	0.6%	0.0%	1.9%	2.5%
10,000 or more treatments	3,281	29.0	0.6%	0.0%	1.9%	2.5%
Unknown	27	0.0	0.8%	-0.4%	2.2%	2.5%
Percentage of Pediatric Patients						
Less than 2%	7,659	43.8	0.6%	0.0%	1.9%	2.5%
Between 2% and 19%	38	0.2	0.6%	0.1%	1.9%	2.6%
Between 20% and 49%	13	0.0	0.2%	0.4%	2.0%	2.6%

More than 50%	51	0.0	0.3%	0.1%	1.9%	2.3%

[1] The Tablo® System will be paid for using the TPNIES under the ESRD PPS for CY 2022. We estimate approximately $2.5 million in spending, of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.
[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the changes to the outlier payment policy described in section II.B.1.c of this final rule is shown in column C. For CY 2022, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.6 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2022 payments as a result of the outlier policy changes.

Column D shows the effect of the annual update to the wage index, as described in section II.B.1.b of this final rule. That is, this column reflects the update from the CY 2021 ESRD PPS wage index using 2018 OMB delineations as finalized in the CY 2021 ESRD PPS final rule, with a basis of the FY 2022 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. The total impact of this change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.7 percent decrease to a 0.5 percent increase due to the annual update to the ESRD PPS wage index.

Column E shows the effect of the final CY 2022 ESRD PPS payment rate update as described in section II.B.1.a of this final rule. The ESRD PPS payment rate update is 1.9 percent, which reflects the ESRDB market basket percentage increase factor for CY 2022 of 2.4 percent and the productivity adjustment of 0.5 percent.

Column F reflects the overall impact, that is, the effects of the outlier policy changes, the updated wage index, and the payment rate update. We expect that overall ESRD facilities will experience a 2.5 percent increase in estimated payments in CY 2022. The categories of types of facilities in the impact table show impacts ranging from a 1.6 percent increase to a 3.3 percent increase in their CY 2022 estimated payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2022, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2022 will be approximately $8.8 billion. This estimate considers a projected decrease in fee-for-service Medicare dialysis beneficiary enrollment of 5.8 percent in CY 2022.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.5 percent overall increase in the CY 2022 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 2.5 percent in CY 2022, which translates to approximately $60 million.

(5) Alternatives Considered

CY 2022 Impacts: 2019 Versus 2020 Claims Data

Each year CMS uses the latest available ESRD claims to update the outlier threshold, budget neutrality factor, and payment rates. Due to the COVID–19 PHE, we compared the impact of using CY 2019 claims against CY 2020 claims to determine if there was any substantial difference in the results that would justify potentially deviating from our longstanding policy to use the latest available data. Analysis suggested that ESRD utilization did not change substantially during the pandemic, likely due to the patients' vulnerability and need for these services. Consequently, we finalized our proposal to use the CY 2020 data because it does not negatively impact ESRD facilities and keeps with our longstanding policy to make updates using the latest available ESRD claims data (86 FR 36414).

Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Application: The Tablo® System—Home Dialysis Machine

As discussed in section II.C.1.a. of the preamble of this final rule, we are approving 1 technology for TPNIES for CY 2022, the Tablo® System. We have provided an estimated impact for the purposes of the Regulatory Impact Analysis, as follows. A Tablo® System that was priced at $40,000 and amortized over 5 useful life years using straight line depreciation would equal $8,000 per year ($40,000/5 = $8,000). Sixty-five percent of the annual cost would equal $5,200 per year ($8,000 * .65 = $5,200 per year). The pre-adjusted per treatment payment amount would equal $33.33 per treatment ($5,200/156 = $33.33 per treatment). The TPNIES amount would therefore equal an estimated $23.92 per treatment ($33.33 – the CY 2022 average per treatment offset amount of $9.50 = $23.83).

Based on February 2021 Shared Systems Data, there were approximately 6,600 Medicare beneficiaries receiving home hemodialysis treatment. If we estimated that this entire population were to use the Tablo® System in CY2022, there would be 1,029,600 treatments (6,600 Medicare beneficiaries * 156 treatments per year = 1,029,600 treatments). Applying the estimated $23.83 per treatment TPNIES amount to the estimated 1,029,600 treatments would result in approximately $25 million in spending ($23.83 * 1,029,600 = $24,535,368). If, for example, 1 percent of this population were to use the Tablo® System in CY 2022, there would be 10,296 treatments (66 Medicare beneficiaries * 156 treatments per year = 10,296 treatments). Applying the $23.83 per treatment TPNIES amount to the 10,296 treatments would result in approximately $246,280 in

spending ($23.83 * 10,296 = $245,354). We believe that 10 percent of this population is a more reasonable estimate. If the estimated 10 percent were to use the Tablo® System in CY 2022, there would be 102,960 treatments (660 Medicare beneficiaries * 156 treatments per year = 102,960 treatments). Applying the estimated $23.83 per treatment TPNIES amount to the 102,960 treatments would result in approximately $2.5 million in spending ($23.83 * 102,960 = $2,453,537), of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.

b. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2021 to estimated payments in CY 2022. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2021 and CY 2022 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2020 data from the Part A and Part B Common Working Files as of February 12, 2021, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2020 claims to 2021 and 2022 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 10 shows the impact of the estimated CY 2022 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2021.

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TABLE 10: Impacts of the Changes in Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2022

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of 2022 Changes in Wage Index (C)	Effect of 2022 Changes in Payment Rate Update (D)	Effect of Total 2022 Final Changes (E)
All Facilities	5,290	315.1	0.0%	1.9%	1.9%
Type					
Freestanding	5,162	309.7	0.0%	1.9%	1.9%
Hospital based	128	5.5	0.1%	1.9%	2.0%
Ownership Type					
Large dialysis organization	4,273	260.7	0.0%	1.9%	1.9%
Regional chain	718	37.7	0.1%	1.9%	2.0%
Independent	170	11.3	-0.1%	1.9%	1.8%
Hospital based[1]	128	5.5	0.1%	1.9%	2.0%
Unknown	1	0.0	-0.3%	1.9%	1.6%
Geographic Location					
Rural	875	49.4	0.0%	1.9%	1.9%
Urban	4,415	265.7	0.0%	1.9%	1.9%
Census Region					
East North Central	885	56.5	-0.2%	1.9%	1.7%
East South Central	429	22.9	-0.3%	1.9%	1.5%
Middle Atlantic	590	34.2	-0.3%	1.9%	1.6%
Mountain	305	19.4	-0.1%	1.9%	1.8%
New England	142	6.5	-0.7%	1.9%	1.2%
Pacific[2]	659	49.1	0.6%	1.9%	2.5%
Puerto Rico and Virgin Islands	3	0.0	0.0%	1.9%	1.9%
South Atlantic	1,245	76.7	0.2%	1.9%	2.1%
West North Central	343	16.5	0.0%	1.9%	1.9%
West South Central	689	33.3	-0.3%	1.9%	1.6%
Facility Size					
Less than 4,000 treatments	602	23.8	-0.2%	1.9%	1.7%
4,000 to 9,999 treatments	2,187	122.0	-0.1%	1.9%	1.8%
10,000 or more treatments	2,495	169.1	0.1%	1.9%	2.0%
Unknown	6	0.2	0.5%	1.9%	2.4%
Percentage of Pediatric Patients					
Less than 2%	5,288	315.1	0.0%	1.9%	1.9%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	2	0.0	-1.3%	1.9%	0.5%

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis

treatments (in thousands). Column C shows the effect of the final CY 2022 wage indices. Column D shows the effect of the CY 2022 ESRD PPS payment rate update. The ESRD PPS payment rate update is 1.9 percent, which reflects the ESRDB market basket percentage increase factor for CY 2022 of 2.4 percent and the productivity adjustment of 0.5 percent.

Column E reflects the overall impact, that is, the effects of the updated wage index and the payment rate update. We expect that overall ESRD facilities will experience a 1.9 percent increase in estimated payments in CY 2022. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 2.5 percent in their CY 2022 estimated payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are updating the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change will have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $60 million will be paid to ESRD facilities in CY 2022 as a result of patients with AKI receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

c. ESRD QIP

(a). Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD dialysis facility services provided to beneficiaries. Although the general methodology that we use to determine a facility's TPS is described in our regulations at 42 CFR 413.178(e), we are finalizing our proposal to codify special scoring policies for PY 2022 at 42 CFR 413.178(h). Under these finalized regulations, we will calculate measure rates for all measures but will not calculate achievement and improvement points for any measures. We will also not calculate or award a TPS for any facility. Finally, we will not reduce payment to any facility for PY 2022.

We believe there will be no effects of the PY 2022 ESRD QIP on ESRD Facilities resulting from these finalized policies because no facilities will receive a TPS or payment reductions for PY 2022.

(b). Effects of the PY 2024 ESRD QIP on ESRD Facilities

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2024 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2024, as codified in our regulations at 42 CFR 413.177.

For the PY 2024 ESRD QIP, we estimate that, of the 7,717 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.3 percent or 1,788 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2024. We are presenting an estimate for the PY 2024 ESRD QIP to update the estimated impact that was provided in the CY 2021 ESRD PPS final rule (85 FR 71481 through 71483). As a result of our finalized policies, the total estimated payment reductions for all the 1,788 facilities expected to receive a payment reduction in PY 2024 would decrease from $18,247,083.76 to approximately $17,104,030.59. Facilities that do not receive a TPS do not receive a payment reduction.

Table 11 shows the overall estimated distribution of payment reductions resulting from the PY 2024 ESRD QIP.

TABLE 11: Estimated Distribution of PY 2024 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,557	75.66%
0.5%	1,338	18.22%
1.0%	357	4.86%
1.5%	70	0.95%
2.0%	23	0.31%

*372 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2024, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there

were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 12) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 12.

TABLE 12: Data Used to Estimate PY 2024 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Hypercalcemia	Jan 2018-Dec 2018	Jan 2019-Dec 2019

For all measures except the SHR clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, and the STrR reporting measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the finalized polices outlined in sections IV.E. and IV.F. of this final rule. Facility reporting measure scores were estimated using available data from CY 2019. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2024 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 13 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2024. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2024 ESRD QIP, the actual impact of the PY 2024 ESRD QIP may vary significantly from the values provided here.

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TABLE 13: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2024

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,717	43.4	7,345	1,788	-0.16%
Facility Type:					
Freestanding	7,339	41.7	7,007	1,685	-0.15%
Hospital-based	378	1.7	338	103	-0.25%
Ownership Type:					
Large Dialysis	5,886	33.6	5,703	1,207	-0.12%
Regional Chain	887	5.3	845	250	-0.20%
Independent	515	2.8	457	228	-0.39%
Hospital-based (non-chain)	378	1.7	338	103	-0.25%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,548	1,457	-0.13%
Small Entities[1]	893	4.5	795	331	-0.33%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,234	203	-0.09%
2) No	6,449	37.1	6,111	1,585	-0.17%
Census Region:					
Northeast	1,060	6.4	993	256	-0.16%
Midwest	1,716	7.9	1,654	426	-0.17%
South	3,506	20.1	3,356	906	-0.17%
West	1,374	8.5	1,283	166	-0.08%
US Territories[2]	61	0.4	59	34	-0.39%
Census Division:					
Unknown	9	0.1	8	4	-0.37%
East North Central	1,213	5.6	1,163	351	-0.21%
East South Central	609	3.2	591	134	-0.13%
Middle Atlantic	859	5.1	801	224	-0.17%
Mountain	428	2.3	404	52	-0.08%
New England	201	1.3	192	32	-0.10%
Pacific	946	6.2	879	114	-0.08%
South Atlantic	1,794	10.4	1,700	493	-0.19%
West North Central	503	2.3	491	75	-0.10%
West South Central	1,103	6.5	1,065	279	-0.17%
US Territories[2]	52	0.3	51	30	-0.40%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,059	201	-0.15%
4,000-9,999 treatments	2,905	11.9	2,901	605	-0.13%
Over 10,000 treatments	3,384	28.9	3,383	981	-0.17%
Unknown	180	0.2	2	1	-0.25%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(c). Effects of the PY 2025 ESRD QIP on ESRD Facilities

For the PY 2025 ESRD QIP, we estimate that, of the 7,717 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.3 percent or 1,788 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2025. The total payment reductions for all the 1,788 facilities expected to receive a payment reduction is approximately $17,104,030.59. Facilities that do not receive a TPS do not receive a payment reduction. Table 14 shows the overall estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP.

TABLE 14: Estimated Distribution of PY 2025 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,557	75.66%
0.5%	1,338	18.22%
1.0%	357	4.86%
1.5%	70	0.95%
2.0%	23	0.31%

*Note: 372 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2025, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 14) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 15.

TABLE 15: Data Used to Estimate PY 2025 ESRD QIP Payment Reductions

Measure	**Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds**	**Performance period**
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Hypercalcemia	Jan 2018-Dec 2018	Jan 2019-Dec 2019

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR reporting measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the policies outlined in section IV.E. and IV.F. of this final rule. Facility reporting measure scores were estimated using available data from CY 2019. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2025 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 16 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2025. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2025 ESRD QIP, the actual impact of the PY 2025 ESRD QIP may vary significantly from the values provided here.

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TABLE 16: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,717	43.4	7,345	1,788	-0.16%
Facility Type:					
Freestanding	7,339	41.7	7,007	1,685	-0.15%
Hospital-based	378	1.7	338	103	-0.25%
Ownership Type:					
Large Dialysis	5,886	33.6	5,703	1,207	-0.12%
Regional Chain	887	5.3	845	250	-0.20%
Independent	515	2.8	457	228	-0.39%
Hospital-based (non-chain)	378	1.7	338	103	-0.25%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,548	1,457	-0.13%
Small Entities[1]	893	4.5	795	331	-0.33%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,234	203	-0.09%
2) No	6,449	37.1	6,111	1,585	-0.17%
Census Region:					
Northeast	1,060	6.4	993	256	-0.16%
Midwest	1,716	7.9	1,654	426	-0.17%
South	3,506	20.1	3,356	906	-0.17%
West	1,374	8.5	1,283	166	-0.08%
US Territories[2]	61	0.4	59	34	-0.39%
Census Division:					
Unknown	9	0.1	8	4	-0.37%
East North Central	1,213	5.6	1,163	351	-0.21%
East South Central	609	3.2	591	134	-0.13%
Middle Atlantic	859	5.1	801	224	-0.17%
Mountain	428	2.3	404	52	-0.08%
New England	201	1.3	192	32	-0.10%
Pacific	946	6.2	879	114	-0.08%
South Atlantic	1,794	10.4	1,700	493	-0.19%
West North Central	503	2.3	491	75	-0.10%
West South Central	1,103	6.5	1,065	279	-0.17%
US Territories[2]	52	0.3	51	30	-0.40%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,059	201	-0.15%
4,000-9,999 treatments	2,905	11.9	2,901	605	-0.13%
Over 10,000 treatments	3,384	28.9	3,383	981	-0.17%
Unknown	180	0.2	2	1	-0.25%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(d). Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(e). Effects on the Medicare Program

For PY 2025, we estimate that the ESRD QIP would contribute approximately $17,104,030.59 in Medicare savings. For comparison, Table 17 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2025. This includes our finalized PY 2022 scoring and payment proposals as described in section IV.D. of this final rule.

TABLE 17: Estimated Payment Reductions Payment Years 2018 through 2025

Payment year	Estimated payment reductions
PY 2025	$17,104,030.59
PY 2024	$17,104,030.59
PY 2023	$15,770,179 (85 FR 71483)
PY 2022	$0[279]
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(f). Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(g). Alternatives Considered

In section IV.D. of this final rule, we are finalizing a special rule to modify the scoring methodology such that no facility will receive a payment reduction for PY 2022. Under this special rule for PY 2022, we will calculate measure rates for all measures for that payment year, but will not use those measure rates to generate an achievement or improvement score, domain scores, or a TPS. We considered retaining our current scoring policy for PY 2022. However, we concluded that this was not feasible because of the EQRS system issues described in section IV.B.2., and additionally, due to the impact of the COVID–19 PHE on some of the PY 2022 ESRD QIP measures, as described more fully in section IV.C. of this final rule. This approach will help to ensure that a facility would not be penalized due to extraordinary circumstances beyond the facility's control.

d. ETC Model

(1). Overview

Under the ESRD PPS under Medicare Part B, a single per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. Under the Physician Fee Schedule, medical management of an ESRD beneficiary receiving dialysis by a physician or other practitioner is paid through the MCP. The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 6114), for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. The changes in this final rule (discussed in detail in section V.B of this final rule) will impact model payment adjustments for PPA Period 3, starting in July 1, 2023.

Under the current ETC Model, there are two payment adjustments designed to increase rates of home dialysis and kidney transplant waitlisting through financial incentives. The HDPA is an upward payment adjustment on certain home dialysis claims for ESRD facilities, as described in the final rule in §§ 512.340 and 512.350, and to certain home dialysis-related claims for Managing Clinicians, as described in the final rule in §§ 512.345 and 512.350, during the initial 3 years of the ETC Model.

The PPA is an upward or downward payment adjustment on certain dialysis and dialysis-related claims submitted by ETC Participants, as described in the final rule in §§ 512.375(a) and 512.380 for ESRD facilities and §§ 512.375(b) and 512.380 for Managing Clinicians, which will apply to claims with claim service dates beginning on July 1, 2022 and increase in magnitude over the duration of the Model. We will assess each ETC Participant's home dialysis rate, as described in the final rule in § 512.365(b), and ETC transplant waitlist rate, as described in § 512.365(c), for each Measurement Year (MY). The ETC Participant's transplant waitlist rate, will be aggregated, as described in § 512.365(e), and the ETC Participant's home dialysis rate will be aggregated, as described in § 512.365(e). The ETC Participant will receive a Modality Performance Score (MPS) based on the weighted sum of the higher of the ETC Participant's achievement score or improvement score for the home dialysis rate and the higher of the ETC Participant's achievement score or improvement score for the transplant waitlist rate, as described in § 512.370(d).

For MY1 and MY2 (January 1, 2021 through July 6, 2022), the achievement scores will be calculated in relation to a set of benchmarks based on the historical rates of home dialysis and inclusion on the transplant waitlist among ESRD facilities and Managing Clinicians located in Comparison Geographic Areas. The improvement scores will be calculated in relation to a set of benchmarks based on the ETC Participant's own historical performance. The ETC Participant's MPS for a MY will determine the magnitude of its PPA during the corresponding 6-month PPA Period, which will begin 6 months after the end of the MY. An ETC Participant's MPS will be updated on a rolling basis every 6 months.

As mentioned in section IV.C.2.b(1) of the Specialty Care Models final rule (85 FR 61351), the intention was to increase achievement benchmarks over time through subsequent notice and

[279] As discussed in section IV.D of this final rule, we are finalizing our proposed special scoring methodology and payment policy for PY 2022. Under this policy, we will not apply any payment reductions to ESRD facilities for PY 2022.

comment rulemaking. In the CY 2022 ESRD PPS proposed rule, the changes listed with bullets were proposed for MY3 (beginning January 1, 2022) through the final MY of ETC Model (MY10).

- Include nocturnal in-center dialysis in the home dialysis rate calculation for Managing Clinicians and ESRD facilities not owned in whole or in part by an ETC LDO.
- Modify the PPA achievement benchmarking methodology:

++Stratify the home dialysis and transplant rate benchmark by the proportion of beneficiaries who are dual-eligible for Medicare and Medicaid, or, receive the Low-Income Subsidy (LIS), resulting in two strata.

++Increase the home dialysis and transplant rate benchmarks by 10 percent for each MY couplet (that is, 1.10 for MY3 and MY4, 1.20 for MY5 and MY6, 1.30 for MY7 and MY8, and 1.40 for MY9 and MY10).

- Modify the PPA improvement benchmarking methodology:

++Health Equity Incentive: Participants can earn 0.5 improvement points in addition to their improvement score for a 5 percentage point increase in the home dialysis rate or transplant rate among dual eligible or LIS recipient beneficiaries.

++Modify improvement calculation to ensure that the Benchmark Year rate cannot be zero, such that improvement is calculable for all participants.

In this final rule, we finalized all of the changes proposed in the CY 2022 ESRD PPS proposed rule, with certain modifications. The two such modifications most likely to affect the impact estimate for the ETC Model are:

- Modify the home dialysis rate calculation by including nocturnal dialysis in the numerator of the home dialysis rate calculation for all ESRD facilities, rather than only those ESRD facilities not owned in whole or in part by an ETC LDO.
- Modify the methodology for the Health Equity Incentive by reducing the threshold to earn the additional 0.5 improvement points from a 5-percentage point increase to a 2.5-percentage point increase from the Benchmark Year to the MY.

More detail on these changes are provided in sections V.B.3.c and V.B.6.c.(2) of this final rule. The ETC Model is not a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they will in the absence of the Model.

(2). Data and Methods

A stochastic simulation was created to estimate the financial impacts of the changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years with complete data available. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

The ESRD facilities and Managing Clinicians datasets were restricted to the following eligibility criteria. Beneficiaries must be residing in the United States, 18 years of age or older, and enrolled in Medicare Part B. Beneficiaries enrolled in Medicare Advantage or other cost or Medicare managed care plans, who have elected hospice, are receiving dialysis for acute kidney injury (AKI) only, with a diagnosis of dementia, who are receiving dialysis in a nursing facility, or reside in a skilled nursing facility were excluded. In addition, beneficiaries who have a diagnosis of and are receiving treatment with chemotherapy or radiation for a vital solid organ cancer were excluded from the transplant rate calculations. Diagnosis of a vital solid organ cancer was defined as a beneficiary that had a claim with any of 39 ICD–10–CM codes ranging from C22.0 through C79.02. Treatment of a vital solid organ cancer was defined as a beneficiary with a claim with any of 2,087 radiation administration ICD–10–PCS codes, 19 chemotherapy administration CPT codes, or 41 radiation administration CPT codes. Last, the HRR was matched to the claim service facility ZIP Code™ or the rendering physician ZIP Code for ESRD facility and Managing Clinician, respectively.[280]

For the modeling exercise used to estimate changes in payment to providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method to identify ESRD facilities with common ownership, the low-volume exclusion threshold, and the aggregation assumptions as CMS is not making changes to these model policies. To clarify OACT's methodology, the ESRD facilities' data were aggregated to the CMS Certification Number (CCN) level for beneficiaries on dialysis identified by outpatient claims with Type of Bill 072X to capture all dialysis services furnished at or through ESRD facilities. Beneficiaries receiving home dialysis services were defined as condition codes 74 and 76 (§ 512.340). Condition code 75 was removed from the home dialysis definition because that billing code is no longer in use. Condition code 80 was removed because we want to exclude beneficiaries who received home dialysis furnished in a SNF or nursing facility. Beneficiaries receiving in-center dialysis services were defined using condition code 71. Two new variables were created: In-center self-dialysis, condition code 72 (§ 512.365) and in-center nocturnal dialysis, based on any of the claims' lines 1–5 HCPCS codes equal to the ''UJ'' modifier. Self-care in training and ESRD self-care retraining, condition codes 73 and 87, respectively, were only included in the denominator for the home dialysis rate calculation. For consistency with the exclusion in § 512.385(a), after grouping within each HRR, aggregated ESRD facilities with less than 132 total attributed beneficiary months during a given MY were excluded. When constructing benchmarks, for consistency with the methodology for aggregating performance for purposes of the PPA calculation, we aggregated all ESRD facilities owned in whole or in part by the same dialysis organization located in the same HRR.

The Managing Clinicians' performance data were aggregated to the Tax Identification Number (TIN) level (for group practices) and the individual National Provider Identifier (NPI) level (for solo practitioners). For purposes of calculating the home dialysis rate, beneficiaries on home dialysis were identified using outpatient claims with CPT® codes 90965 and 90966 (§ 512.345). Beneficiaries receiving in-center dialysis were identified by outpatient claims with CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 (§ 512.360). Last, following the low-volume threshold described in § 512.385(b), after grouping within each HRR, Managing Clinicians with less than 132 total attributed beneficiary months during a given MY were excluded.

The Scientific Registry of Transplant Recipients (SRTR) transplant waitlist data were obtained from the Center for Clinical Standards and Quality (CCSQ). To construct the transplant waitlist rate, the numerator was based on per-patient counts and included every addition to the waitlist for a patient in any past year. The waitlist counts for the

[280] ZIP Code is a trademark owned by the United States Postal Service.

numerator included waitlists for kidney transplants, alone or with another organ, active and inactive records, multi-organ listings, and patients that have subsequently been removed from the waitlist. The denominator was a unique count of prevalent dialysis patients as of the end of the year. Only patients on dialysis as of December 31st for the selected year were included. Facility attribution was based on the facility the patient was admitted to on the last day of the year.

For MY1 and MY2, the home dialysis score and transplant score for the PPA were calculated using the following methodology for the ESRD facilities and Managing Clinicians. ETC Participant behavior for each year was simulated by adjusting the ETC Participant's baseline home dialysis (or transplant) rate for a simulated statistical fluctuation and then summing with the assumed increase in home dialysis (or transplant) rate multiplied by a randomly generated improvement scalar. The achievement and improvement scores were assigned by comparing the ETC Participant's simulated home dialysis (or transplant) rate for the MY to the percentile distribution of home dialysis (or transplant) rates in the prior year. Last, the MPS was calculated using the weighted sum of the higher of the achievement or improvement score for the home dialysis rate and the transplant waitlist rate. The home dialysis rate constituted two-thirds of the MPS, and the transplant rate one-third of the MPS.

For MY3 through MY10, the home dialysis rate calculation accounts for modifications in this final rule compared to the CY 2022 ESRD PPS proposed rule. The revisions include changing the numerator for the home dialysis rate from the home dialysis beneficiary months to the home dialysis beneficiary months + 0.5 (in-center self-dialysis beneficiary months) + 0.5* (nocturnal in-center dialysis beneficiary months), such that 1-beneficiary year is comprised of 12-beneficiary months for all ETC Participants.

The number of beneficiaries on in-center self-dialysis who met the eligibility criteria for the ETC Model was very small, ranging from 102 to 277 over the period 2012–2019 and decreasing 89.9 percent to 22 beneficiaries in 2020 (based on preliminary 2020 data at CMS). With such a small sample size, the growth rate vacillated significantly. In addition, the in-center nocturnal dialysis UJ modifier code did not become effective until January 1, 2017; therefore, there were insufficient data to generate growth rate assumptions. The in-center nocturnal dialysis beneficiary growth rate decreased by 91.3 percent in 2020. As a solution to these data limitations, to simulate the impact of incorporating in-center self-dialysis and in-center nocturnal dialysis for the purpose of the savings to Medicare estimate, the simulation assumed any given ESRD facility or Managing Clinician will have a one percent chance of receiving an increased achievement score due to this policy.

The overall process for generating achievement and improvement scoring followed modeling from section VI.C.2 of the Specialty Care Models final rule (85 FR 61352), with the exception of the following changes proposed in the CY 2022 ESRD PPS proposed rule, which we are finalizing in this final rule.

Beginning for MY3 and beyond, the achievement benchmarking methodology included two modifications. First, the home dialysis rate and transplant waitlist rate benchmarks were increased by a total of 10 percent relative to ESRD facilities and Managing Clinicians not selected for participation, every two MYs. To clarify, no changes to the achievement benchmarking methodology were made to MYs 1 and 2. The latter MY couplets' achievement benchmarking included the following preset benchmark updates:

- MYs 3 and 4: Comparison Geographic Area percentiles*1.10,
- MYs 5 and 6: Comparison Geographic Area percentiles*1.20,
- MYs 7 and 8: Comparison Geographic Area percentiles*1.30, and
- MYs 9 and 10: Comparison Geographic Area percentiles*1.40.

The percentiles represented the 30th, 50th, 75th, and 90th percentile of the home dialysis rate and transplant rate for ESRD facilities and Managing Clinicians not selected for participation. The preset benchmark updates method provides greater certainty to ETC Participants than the rolling updates described in section IV.C.2.b(3) of the Specialty Care Models final rule (85 FR 61353).

Second, we incorporated two proxies for socioeconomic status, dual eligibility status or receipt of the Low Income Subsidy (LIS), as part of the achievement benchmarking starting for MY3 and beyond. Dual eligibility status was defined as a Medicare beneficiary with any of the following full-time dual type codes: 02 = Eligible is entitled to Medicare Qualified Medicare Beneficiary (QMB) and Medicaid coverage including prescription drugs, 04 = Eligible is entitled to Medicare Specified Low-Income Medicare Beneficiary (SLMB) and Medicaid coverage including prescription drugs, or 08 = Eligible is entitled to Medicare Other dual eligible with Medicaid coverage including prescription drugs. Separately, a yes/no indicator was created for any beneficiary that was either deemed or determined by the Social Security Administration (SSA) to be receiving the LIS. The home dialysis rate and transplant waitlist rate achievement benchmarks were then stratified by the proportion of attributed beneficiaries who are dual-eligible or receive the LIS. Two strata were created with a cutpoint of approximately 50 percent for participants with any dual-eligible or LIS recipient beneficiaries and those who do not have beneficiaries meeting these two socioeconomic status proxies.

Third, a Health Equity Incentive was added to improvement scoring starting in MY3. For the purpose of the estimates in this Regulatory Impact Analysis, we incorporated a random variable to simulate each ETC Participant's baseline variation and behavioral improvement for each MY. If the participant's simulated improvement behavior in MY3 through MY10 was greater than 2.5 percent, then the participant received a 0.5-point increase on their improvement score, allowing for a maximum of 2.0 total points. The threshold for receiving the Health Equity Incentive was reduced from the 5-percentage point threshold proposed in the CY 2022 ESRD PPS proposed rule to a 2.5-percentage point threshold in this final rule.

For all MYs, the transplant waitlist benchmarks were annually inflated by approximately 3-percentage points growth. This was a modification from section VI.C.2 of the Specialty Care Models final rule (85 FR 61352), where the waitlist benchmarks were annually inflated by approximately 2-percentage points growth observed during years 2017 through 2019 in the CCSQ data, to project rates of growth. The additional 1 percentage point growth in this final rule was included to account for uncertainty from the COVID–19 PHE disruption and section 17006 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), which amended the Act to increase enrollment options for individuals with ESRD into Medicare Advantage. To clarify, applying the 3-percentage point annual growth from the median transplant waitlist rate across HRR condensed facilities grew from 8 percent in 2017 to 11 percent in 2018 to 14 percent in 2019 (that is, not a growth rate of 1.03 percent per year).

To assess the impact of the COVID–19 PHE on the kidney transplant waitlist, we analyzed data from the

United Network for Organ Sharing (UNOS).[281] The UNOS data suggest that the number of new patients added to the kidney transplant waitlist steadily decreased between the weeks of March 15, 2020 through May 10, 2020, when between 16 to 81 percent of patients listed on the weekly kidney transplant waitlist became inactive due to COVID–19 precautions. During July through December 2020, the number of new patients added to the kidney transplant waitlist increased to near pre-pandemic levels with an average of less than 3 percent of patients listed as inactive due to COVID–19. Anomalous dips in the number of new patients added to the kidney transplant waitlist were observed during the weeks of November 22, 2020 and December 27, 2020, which correspond with Federal holidays in addition to a period that Americans were asked to social distance to slow the spread of COVID–19. Continuing into the first quarter of 2021, new additions to the kidney transplant waitlist remained at approximately pre-pandemic rates. Therefore, we assume that the number of new patients added to the waitlist will not decrease as a result of the pandemic and the linear 2-percentage point growth rate for the transplant waitlist calculated using years 2017 through 2019 CCSQ data remains a reasonable assumption for baseline growth going forward. In the final rule, we also included a 1 percent increase to the standard error to account for a new variation assumption to address how year-over-year changes could fluctuate at the ESRD facility or Managing Clinician level, which was potentially exacerbated by the exclusion criteria (that is, residents of a nursing facility, receiving dialysis in a skilled nursing facility, dialysis for AKI only) applied to the updated model data source used for estimates in this final rule.

No changes were made to the payment structure for the HDPA calculation in the final rule (§ 512.350). As such, the HDPA was calculated using the home dialysis and home dialysis-related payments adjusted by decreasing amounts (3, 2, and 1 percent) during each of the first 3 years of the Model.

The kidney disease patient education services utilization and cost data were identified by HCPCS codes G0420 and G0421, to capture face-to-face individual and group training sessions for chronic kidney disease beneficiaries on treatment modalities. The home dialysis training costs for incident beneficiaries on home dialysis for Continuous Ambulatory Peritoneal Dialysis (CAPD) or Continuous Cycler-Assisted Peritoneal Dialysis (CCPD) were defined using CPT® codes 90989 and 90993 for complete and incomplete training sessions, respectively.

Data from CY 2019 were used to project baseline expenditures (that is, expenditures before the proposed changes were applied) and the traditional FFS payment system billing patterns were assumed to continue under current law.

(3). Medicare Estimate—Primary Specification, Assume Preset Benchmark Updates

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[281] UNOS. 2021. COVID–19 and Solid Organ Transplants. Transplant and Waitlist Data Visualizations. *https://unos.org/covid/.*

TABLE 18. Estimates of Medicare Program Savings (Rounded $M) for ETC MODEL

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**6.5 Year Total***
Net Impact to Medicare Spending	15	9	-2	-10	-12	-18	-9	-28
Overall PPA Net & HDPA	14	7	-4	-12	-15	-21	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-4	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	5
Clinician PPA Net		0	-1	-1	-2	-2	-1	-8
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-21	-25	-31	-39	-21	-146
Facility Upward Adjustment		5	12	15	18	20	10	80
Facility PPA Net		-3	-9	-10	-13	-19	-11	-65
Facility HDPA	14	10	6					30
Total PPA Downward Adjustment		-9	-22	-28	-34	-42	-23	-159
Total PPA Upward Adjustment		6	13	16	19	21	11	86
Total PPA Net		-4	-10	-12	-15	-21	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The Kidney Disease Patient Education Services Costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

TABLE 19: Difference from the Proposed Rule (86 FR 36425) (Rounded $M)

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**4.5 Year Total***
Net Impact to Medicare Spending			1	2	2	3	2	10
Overall PPA Net & HDPA			1	2	2	3	2	10
Total PPA Downward Adjustment			1	1	1	1	1	4
Total PPA Upward Adjustment			0	1	1	2	1	5
Total PPA Net			1	2	2	3	2	10
Total HDPA								0

* Model changes effective for MY 3. Payments adjusted beginning in PPA Period 3, effective July 1, 2023 going forward. No changes to the HDPA. No changes to the Kidney Disease Patient Education Services Costs or the HD Training Costs. See Table 18 for additional footnotes.

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Table 18 summarizes the estimated impact of the ETC Model when assuming preset benchmark updates where the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate the Medicare program will save a net total of $43 million from the PPA and HDPA between January 1, 2021 and June 30, 2027, less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. In Table 18 and Table 19, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for both tables were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag.

Table 19 is provided to isolate the total impact of the changes in this final rule for years 2023 going forward by calculating the difference from our final estimates in Table 18 less totals from the

estimates reported in Table 18 of the CY 2022 ESRD PPS proposed rule (86 FR 36425) that used the same years of data, but without the changes from the CY 2022 ESRD PPS proposed rule to this final rule. To clarify, the CY 2022 ESRD PPS proposed rule estimates are not the estimates reported in Table 19 of the Specialty Care Models final rule (85 FR 61354); the final rule used data from CYs 2016 and 2017 and this final rule used the most recent data available, from CYs 2018 and 2019. There was no impact reported in years 2021 and 2022 since the payment adjustments were not effective until MY3. In addition, the changes did not apply to the HDPA or the Kidney Disease Patient Education Services Costs and HD Training Costs. As expected, Table 19 shows that the changes had a small effect on Medicare savings; a reduction of $10 million in savings for the net impact to Medicare spending over the 4.5-year period can be attributed to the changes in this final rule from the CY 2022 ESRD PPS proposed rule.

As was the case in the Specialty Care Models final rule (85 FR 61353), the projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary FFS effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

Returning to Table 18, as anticipated, the expected Medicare program savings were driven by the net effect of the Facility PPA; a reduction in Medicare spending of $65 million over the period from July 1, 2022 through June 30, 2027. In comparison, the net effect of the Clinician PPA was only $8 million in Medicare savings. This estimate was based on an empirical study of historical home dialysis utilization and transplant waitlist rates for Medicare FFS beneficiaries that CMS virtually attributed to ESRD facilities and to Managing Clinicians based on the plurality of associated spending at the beneficiary level. We analyzed the base variation in those facility/practice level measures and simulated the effect of the payment policy assuming providers and suppliers respond by marginally increasing their share of patients utilizing home dialysis. Random variables were used to vary the effectiveness that individual providers and suppliers might show in such progression over time and to simulate the level of year-to-year variation already noted in the base multi-year data that was analyzed. The uncertainty in the projection was illustrated in sections VII.C.2.b.(3)(a) and VII.C.2.b.(3)(b) of the Specialty Care Models final rule (85 FR 61354), respectively, through alternate scenarios assuming that the benchmarks against which ETC Participants are measured were to not be updated. In those sensitivity analyses, we analyzed a modified version of the model that included a fixed benchmark for the home dialysis and transplant waitlist rates as well as a separate sensitivity analysis that assumed a rolling benchmark for the home dialysis rate and a fixed benchmark for the transplant waitlist rate.

For this final rule, we are continuing with the approach applied in the CY 2022 ESRD PPS proposed rule by modeling a preset benchmark growth rate in this rule but continue to incorporate sensitivity to a range of potential behavioral changes for the home dialysis rate and transplant waitlist rate for ETC facilities and Managing Clinicians assumed to participate in the model. Kidney disease patient education services on treatment modalities and home dialysis (HD) training for incident dialysis beneficiaries are relatively small outlays and were projected to represent only relatively modest increases in Medicare spending each year.

The key assumptions underlying the impact estimate are that each aggregation group's share of total maintenance dialysis provided in the home setting was assumed to grow by up to an assumed maximum growth averaging 3-percentage points per year. Factors underlying this assumption about the home dialysis growth rate include: known limitations that may prevent patients from being able to dialyze at home, such as certain common disease types that make peritoneal dialysis impractical (for example, obesity); current equipment and staffing constraints; and the likelihood that a patient new to maintenance dialysis starts dialysis at home compared to the likelihood that a current dialysis patient who dialyzes in center switches to dialysis at home. In any given trial of the simulation, the maximum growth rate was chosen from a uniform distribution of 0 to 5-percentage points per year. Preliminary data from CMS show that the growth rate for home dialysis was 3.9 percent in CY 2020 for beneficiaries meeting the eligibility criteria for the ETC Model. This growth rate is within range to what was observed prior to the establishment of the Advancing American Kidney Health initiative in 2019 and it also shows that the COVID–19 PHE did not cause the home dialysis growth assumption to become invalid. The 3-percentage point per year average max growth rate will, in effect, move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (for example, Bend, Oregon HRR at about 25 percent), which we believe is a reasonable upper bound on growth over the duration of the ETC Model for the purposes of this actuarial model.

Aggregation groups were assumed to achieve anywhere from zero to 100 percent of such maximum growth in any given year. Thus, the average projected growth for the share of maintenance dialysis provided in the home was 1.5-percentage points per year (expressed as the percentage of total dialysis). In contrast, we do not include an official assumption that the overall number of kidney transplants will increase and provide justification for this assumption in sections VI.C.2.b.(4) and VI.C.2.b.(5) of the Specialty Care Models final rule (85 FR 61355). However, as part of the sensitivity analysis for the savings calculations for the model, we laid out a different savings scenario if the ETC Learning Collaborative described in VI.C.2.b.(6) of the Specialty Care Models final rule (85 FR 61355) were to be successful in decreasing the discard rate of deceased donor kidneys and increasing the utilization rate of deceased donor kidneys that have been retrieved.

(4). Sensitivity Analysis: Medicare Savings Estimate—Results for the 10th and 90th Percentiles

Using the primary specification for the Medicare estimate with preset benchmark updates for home dialysis and transplant waitlist rates, we compared the results for the top 10th and 90th percentiles of the 400 individual simulations to the average of all simulation results reported in Table 18. Since the impact on Medicare spending for the ETC Model using the present benchmark updates is estimated to be in savings rather than losses, the top 10th and 90th percentiles represent the most optimistic and conservative projections, respectively. The overall net PPA and HDPA for the top 10th and 90th percentiles using the present benchmark updates method are $102 million in savings and $9 million in losses (encompassing the mean estimate of $43 million in savings in Table 18). The overall uncertainty of the impact of the model is further illustrated in Table 19, the change from the CY 2022 ESRD

PPS proposed rule, where the mean $10 million dollars in savings reported for the Overall PPA Net & HDPA has $64 million in savings and $97 million in losses, for the top 10th and 90th percentiles, respectively.

(5). Effects on the Home Dialysis Rate

The two changes in this final rule have the potential to increase ETC Participants' home dialysis rate, therefore reducing the overall savings to Medicare estimate. First, this final rule modifies the home dialysis rate equation by adding 0.5 multiplied by the sum of the self-dialysis beneficiary months and the in-center nocturnal dialysis beneficiary months to the numerator such that 1-beneficiary year is comprised of 12-beneficiary months for Managing Clinicians and all ESRD facilities, regardless of ownership.

However, less than 1 percent of beneficiaries eligible for attribution into the ETC Model were receiving either self-dialysis or nocturnal in-center dialysis in CY 2019. In addition, in CY 2020, the annual growth rate decreased by 89.9 and 91.3 percent for beneficiaries receiving self-dialysis or in-center nocturnal dialysis, respectively. The sharp decline in these dialysis modalities is potentially in response to the COVID–19 pandemic. The low historical take-up for self-dialysis and shortage of historical years for in-center nocturnal dialysis (that is, a nocturnal dialysis claims line instruction became effective in 2017) result in these modifications having an insignificant impact on the savings to Medicare.

The second change in this final rule that has the potential to generate higher PPA scores for a limited subset of providers and therefore a small negative impact on estimated savings for the Model is the Health Equity Incentive. The Health Equity Incentive proposed in the CY 2022 ESRD PPS proposed rule (86 FR 36427) would have rewarded ETC Participants with an additional 0.5 points to their improvement score who improved the home dialysis rate (or transplant rate) among their attributed beneficiaries who are dual eligible or receive the LIS by at least 5 percentage points between the Benchmark Year to the MY. In this final rule, the threshold to earn the 0.5 improvement points was reduced to a 2.5-percentage point increase from the Benchmark Year to the MY. The $10 million decrease in the savings to Medicare estimate in this final rule relative to the CY 2022 ESRD PPS proposed rule was primarily due to the change in the Health Equity Incentive threshold.

(6). Effects on Kidney Transplantation

Kidney transplantation is considered the optimal treatment for most ESRD beneficiaries. The PPA includes a one-third weight on the ESRD facilities' or Managing Clinician's transplant waitlist rate, with the ultimate goal of increasing the rate of kidney transplantation. However, the changes in this final rule do not impact our decision in the CY 2022 ESRD PPS proposed rule or the Specialty Care Models final rule to not include an assumption that the overall number of kidney transplants will increase. The number of ESRD patients on the kidney transplant waitlist has for many years far exceeded the annual number of transplants performed. Transplantation rates have not increased to meet such demand because of the limited supply of deceased donor kidneys. The U.S. Renal Data System [282] reported 22,393 kidney transplants in 2018 compared to a kidney transplant waiting list [283] of over 98,000. Refer to section VI.C.2.b(4) in the Specialty Care Models final rule (85 FR 61355) for a detailed justification for our assumption that the overall number of kidney transplants will not increase in response to ESRD facilities and Managing Clinicians participating in the ETC Model.

(7). Effects of the Transplant Rate

The ETC Model continues to include the transplant rate described in the Specialty Care Models final rule (§ 512.365).

The change in this final rule that has the potential to generate higher scores for a limited subset of ETC Participants and therefore a small reduction in the estimated savings for the Model relative to the CY 2022 ESRD PPS proposed rule is the modification to the Health Equity Incentive threshold. By lowering the threshold for earning the Health Equity Incentive threshold in this final rule relative to the threshold proposed in the CY 2022 ESRD PPS proposed rule, more ETC Participants have the potential to earn the additional 0.5 points to their improvement score.

(8). Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes to the ETC Model finalized in this final rule relative to the Specialty Care Models final rule do not impact the findings reported for the effects of the ETC Model on the Kidney Disease Patient education services and HD training add-ons described in section VI.C.2.b(6) in the Specialty Care Models final rule (85 FR 61356–57).

(9). Effects on Medicare Beneficiaries

The changes in this final rule relative to the CY 2022 ESRD PPS proposed rule could incentivize ESRD facilities and Managing Clinicians serving dual eligible or LIS recipient Medicare beneficiaries to potentially improve access to care for those beneficiaries. The final rule's changes could also marginally improve uptake of the in-center nocturnal dialysis treatment modality since this dialysis method was not directly incentivized (that is, accounted for in the home dialysis rate for all ESRD facilities) under the ETC Model. The changes made to the final rule may have marginally increased uptake of in-center nocturnal dialysis for ESRD facilities owned in whole or in part by an ETC LDO relative to the CY 2022 ESRD PPS proposed rule, which had proposed to exclude ESRD facilities owned in whole or in part by an ETC LDO from the in-center nocturnal dialysis policy.

As noted in section VI.C.3.B of the Specialty Care Models final rule (85 FR 61357), we continue to anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same for most beneficiaries under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the ETC Model and to hold beneficiaries harmless from any effect of these payment adjustments on cost sharing. In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis, or nocturnal in-center dialysis, as opposed to in-center dialysis. Studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; as well as better overall, physical, and psychological health in comparison to other dialysis options.

(10). Alternatives Considered

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of

[282] United States Renal Data System. 2020. ''ADR Reference Table E6 Renal Transplants by Donor Type.'' *https://adr.usrds.org/2020/reference-tables.*

[283] Organ Procurement and Transplantation Network. 2021. ''Current US Waiting List, Overall by Organ.'' *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.*

these alternatives and the rationale for each of our policies.

This final rule addresses a model specific to ESRD. It provides descriptions of the requirements that we will waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives that we considered. We carefully considered the alternatives to this final rule, including the degree that benchmark targets should be prospectively updated to provide greater transparency to ETC Participants while preserving the expectation for model net savings for the program. For context related to alternatives previously considered when establishing the ETC Model we refer readers to the Specialty Cares Models final rule (85 FR 61114) for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy preceding the limited modifications proposed here.

D. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

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TABLE 20: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2022)	
Category	**Transfers**
Annualized Monetized Transfers	$230 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$60 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2022	
Category	**Transfers**
Annualized Monetized Transfers	$0
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2024	
Category	**Transfers**
Annualized Monetized Transfers	-$17 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2025	
Category	**Transfers**
Annualized Monetized Transfers	-$17 million
From Whom to Whom	Federal government to ESRD providers
ETC Model for Jan 1, 2023 through June 30, 2027 Impacts of Changes in the Final Rule	
Category	**Transfers**
Annualized Monetized Transfers	-$2.00 million
From Whom to Whom	Federal government to ESRD facilities and Managing Clinicians

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In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

E. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $41.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's website at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $41.5 million).

When viewed as individual entities, as opposed to being a part of a LDO, there are approximately 1,295 (~17 percent of total number of ESRD facilities) ESRD facilities that provide fewer than 4,000 treatments per year. With a low volume payment adjustment, each facility generates revenue from dialysis treatments of ~$1.26 million per year per facility. This is shown in the Table 21.

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TABLE 21: Revenue Table for Low Volume ESRD Facilities for CY 2022 ESRD PPS Final Rule

ESRD Facility size based on # of dialysis treatments	# of low volume ESRD Facilities per Table 9	% of total number of ESRD facilities	~Individual ESRD facility revenue per treatment (including low volume adjustment)	~Annual total treatment revenue per ESRD facility based on 3999 treatments or less	~Total annual treatment revenue to all low volume ESRD facilities
< 4000	1,295	~17%	$320	$1.28 M	$1.6B

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We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 9. Using the definitions in this ownership category, we consider 515 facilities that are independent and 378 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $41.5 million in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.3 percent increase in payments for CY 2022. An independent facility (as defined by ownership type) is estimated to receive a 1.1 percent increase in payments for CY 2022.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $52 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,788 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2024 ESRD QIP, 331 are ESRD small entity facilities. We present these findings in Table 11 (''Estimated Distribution of PY 2024 ESRD QIP Payment Reductions'') and Table 13 (''Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2024'').

For ETC Model, this final rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities and that the greater majority of ESRD facilities are not small entities. Throughout the final rule we describe how the adjustments to certain payments for dialysis services and dialysis-related services furnished to ESRD beneficiaries may affect Managing Clinicians and ESRD facilities participating in the ETC Model. The great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business (having minimum revenues of less than $8 million to $41.5 million in any 1 year, varying by type of provider and highest for hospitals) with a minimum threshold for small business size of $41.5 million (*https://www.sba.gov/document/support--table-size-standards http://www.sba.gov/content/small-businesssize-standards*). The great majority of ESRD facilities are not small entities, as they are owned, partially or entirely by entities that do not meet the SBA definition of small entities.

The HDPA in the ETC Model is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA in the ETC Model, which includes both positive and negative adjustments on payments for dialysis services and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year.

The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same TIN within a Selected Geographic Area. This aggregation policy increases the number of beneficiary months, and thus statistical reliability, of the ETC Participant's home dialysis and transplant rate for ESRD facilities that are owned in whole or in part by the same dialysis organization and for Managing Clinicians that share a TIN with other Managing Clinicians.

Taken together, the low volume threshold exclusions and aggregation policies previously described, coupled with the fact that the ETC Model will affect Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of the final rule will not have a significant impact on spending for a substantial number of small entities (defined as greater than 5 percent impact).

Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is

located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 122 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 122 rural hospital-based dialysis facilities will experience an estimated 1.0 percent increase in payments.

Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This final rule does not mandate any requirements for State, local, or tribal governments in the aggregate, or by the private sector. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or tribal.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

H. Congressional Review Act

This final rule 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 has been transmitted to the Congress and the Comptroller General for review.

IX. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and is posted on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov*.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2021.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.177 is amended by revising paragraph (a) introductory text to read as follows:

§ 413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under § 413.171, except for those renal dialysis services furnished during payment year 2022, in the case of an ESRD facility that does not earn enough points under the program described at § 413.178 to meet or exceed the minimum total performance score (as defined at § 413.178(a)(8)) established by CMS for a payment year (as defined at § 413.178(a)(10)), payments otherwise made to the facility under § 413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

* * * * *

■ 3. Section 413.178 is amended by adding paragraph (h) to read as follows:

§ 413.178 ESRD quality incentive program.

* * * * *

(h) *Special rule for payment year 2022.* (1) CMS will calculate a measure rate for all measures specified by CMS under paragraph (c) of this section for the PY 2022 ESRD QIP but will not score facility performance on any of those measures or calculate a TPS for any facility under paragraph (e) of this section.

(2) CMS will not establish a mTPS for PY 2022.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 4. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

■ 5. Section 512.160 is amended by adding paragraph (a)(9) and revising paragraph (b)(6) to read as follows:

§ 512.160 Remedial action.

(a) * * *

(9) For the ETC Model only, 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.

(b) * * *

(6) In the ETC Model only:

(i) Terminate the ETC Participant from the ETC Model.

(ii) Suspend or terminate the ability of the ETC Participant, pursuant to § 512.397(c), to reduce or waive the coinsurance for kidney disease patient education services.

* * * * *

■ 6. Section 512.310 is amended by adding definitions for ''Clinical staff'', ''Health Equity Incentive'', and

''Qualified staff'' in alphabetical order to read as follows:

§ 512.310 Definitions.

* * * * *

Clinical staff means a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

* * * * *

Health Equity Incentive means the amount added to the ETC Participant's improvement score, calculated as described in § 512.370(c)(1), if the ETC Participant's aggregation group demonstrated sufficient improvement on the home dialysis rate or transplant rate for attributed beneficiaries who are dual eligible or Medicare Low Income Subsidy (LIS) recipients between the Benchmark Year and the MY.

* * * * *

Qualified staff means both clinical staff and any qualified person (as defined at § 410.48(a) of this chapter) who is an ETC Participant.

* * * * *

■ 7. Section 512.360 is amended by revising paragraph (c)(2)(ii) introductory text and adding paragraph (c)(2)(iii) to read as follows:

§ 512.360 Beneficiary population and attribution.

* * * * *

(c) * * *

(2) * * *

(ii) For MY1 and MY2, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician with whom the beneficiary has had the most claims between the start of the MY and the month in which the beneficiary received the transplant for all months between the start of the MY and the month of the transplant.

* * * * *

(iii) For MY3 through MY10, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary in the 365 days preceding the date in which the beneficiary received the transplant.

(A) If no Managing Clinician has had the most claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant.

(B) If no Managing Clinician had the most claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, and more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians.

(C) The Pre-emptive LDT Beneficiary is considered eligible for attribution under this paragraph (c)(2)(iii) if the Pre-emptive LDT Beneficiary has at least 1-eligible month during the 12-month period that includes the month of the transplant and the 11 months prior to the month of the transplant. An eligible month refers to a month during which the Pre-emptive LDT Beneficiary not does not meet exclusion criteria in paragraph (b) of this section.

■ 8. Section 512.365 is amended by revising paragraphs (b)(1)(ii), (b)(2)(ii), (c)(1)(i)(A), (c)(1)(ii)(A), (c)(2)(i)(A), and (c)(2)(ii)(A)(*1*) and (*2*) to read as follows:

§ 512.365 Performance assessment.

* * * * *

(b) * * *

(1) * * *

(ii) For MY1 and MY2, the numerator is the total number of home dialysis treatment beneficiary years plus one half the total number of self dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. For MY3 through MY10, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with Type of Bill 072X and condition codes 74 or 76.

(B) Self dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(C) Nocturnal in center dialysis beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received nocturnal in center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received nocturnal in center dialysis are identified by claims with Type of Bill 072X and modifier UJ.

* * * * *

(2) * * *

(ii) For MY1 and MY2, the numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY plus one half the total number of self dialysis treatment beneficiary years. For MY3 through MY10, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with CPT codes 90965 or 90966.

(B) Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(C) Nocturnal in center dialysis beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received nocturnal in center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary

months. Months in which an attributed ESRD Beneficiary received nocturnal in center dialysis are identified by claims with Type of Bill 072X and modifier UJ.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY.

(*1*) An attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer in an MY if the beneficiary had any of the following diagnosis codes on any claim during the MY or the 6 months prior to the start of the MY: C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8, C22.9, C34.10–C34.12, C34.2, C34.30–C34.32, C34.80–C34.82, C34.90–C34.92, C38.0, C38.8, C46.50–C46.52, C64.1, C64.2, C64.2, C78.00–C78.02, C78.7, C79.00–C79.02, C7A.090, C7A.093, or C7B.02.

(*2*) An attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer during the MY if the beneficiary had a claim with any of the following procedure codes on any claim during the MY or the 6 months prior to the start of the MY:

(*i*) CPT® 96401–96402, 96405–96406, 96409, 96411, 96413, 96415–96417, 96420, 96422–26423, 96425, 96440, 96446, 96549, 77373, 77401–77402, 77407, 77412, 77423, 77424–77425, 77520, 77522–77523, 77525, 77761–77763, 77770–77772, 77778, 77789, 77799, 79005, 79101, 79200, 79300, 79403, 79440, 79445, 79999.

(*ii*) ICD–10–PCS® DB020ZZ, DB021ZZ, DB022ZZ, DB023Z0, DB023ZZ, DB024ZZ, DB025ZZ, DB026ZZ, DB1297Z, DB1298Z, DB1299Z, DB129BZ, DB129CZ, DB129YZ, DB12B6Z, DB12B7Z, DB12B8Z, DB12B9Z, DB12BB1, DB12BBZ, DB12BCZ, DB12BYZ, DB22DZZ, DB22HZZ, DB22JZZ, DBY27ZZ, DBY28ZZ, DBY2FZZ, DBY2KZZ, DB070ZZ, DB071ZZ, DB072ZZ, DB073Z0, DB073ZZ, DB074ZZ, DB075ZZ, DB076ZZ, DB1797Z, DB1798Z, DB1799Z, DB179BZ, DB179CZ, DB179YZ, DB17B6Z, DB17B7Z, DB17B8Z, DB17B9Z, DB17BB1, DB17BBZ, DB17BCZ, DB17BYZ, DB27DZZ, DB27HZZ, DB27JZZ, DBY77ZZ, DBY78ZZ, DBY7FZZ, DBY7KZZ, DF000ZZ, DF001ZZ, DF002ZZ, DF003Z0, DF003ZZ, DF004ZZ, DF005ZZ, DF006ZZ, DF1097Z, DF1098Z, DF1099Z, DF109BZ, DF109CZ, DF109YZ, DF10B6Z, DF10B7Z, DF10B8Z, DF10B9Z, DF10BB1, DF10BBZ, DF10BCZ, DF10BYZ, DF20DZZ, DF20HZZ, DF20JZZ, DFY07ZZ, DFY08ZZ, DFY0CZZ, DFY0FZZ, DFY0KZZ, DT000ZZ, DT001ZZ, DT002ZZ, DT003Z0, DT003ZZ, DT004ZZ, DT005ZZ, DT006ZZ, DT1097Z, DT1098Z, DT1099Z, DT109BZ, DT109CZ, DT109YZ, DT10B6Z, DT10B7Z, DT10B8Z, DT10B9Z, DT10BB1, DT10BBZ, DT10BCZ, DT10BYZ, DT20DZZ, DT20HZZ, DT20JZZ, DTY07ZZ, DTY08ZZ, DTY0CZZ, DTY0FZZ, DW020ZZ, DW021ZZ, DW022ZZ, DW023Z0, DW023ZZ, DW024ZZ, DW025ZZ, DW026ZZ, DW1297Z, DW1298Z, DW1299Z, DW129BZ, DW129CZ, DW129YZ, DW12B6Z, DW12B7Z, DW12B8Z, DW12B9Z, DW12BB1, DW12BBZ, DW12BCZ, DW12BYZ, DW22DZZ, DW22HZZ, DW22JZZ, DWY27ZZ, DWY28ZZ, DWY2FZZ, DW030ZZ, DW031ZZ, DW032ZZ, DW033Z0, DW033ZZ, DW034ZZ, DW035ZZ, DW036ZZ, DW1397Z, DW1398Z, DW1399Z, DW139BZ, DW139CZ, DW139YZ, DW13B6Z, DW13B7Z, DW13B8Z, DW13B9Z, DW13BB1, DW13BBZ, DW13BCZ, DB13BYZ, DW23DZZ, DW23HZZ, DW23JZZ, DWY37ZZ, DWY38ZZ, DWY3FZZ, DW050ZZ, DW051ZZ, DW052ZZ, DW053Z0, DW053ZZ, DW054ZZ, DW055ZZ, DW056ZZ, DWY57ZZ, DWY58ZZ, DWY5FZZ, DWY5GDZ, DWY5GFZ, DWY5GGZ, DWY5GHZ, DWY5GYZ.

* * * * *

(ii) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

* * * * *

(2) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD

Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

* * * * *

(ii) * * *

(A) * * *

(*1*) Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

(*2*) MY1 and MY2, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. For MY3 through MY10, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant, excluding beneficiaries who had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

* * * * *

■ 9. Section 512.370 is amended by revising paragraphs (b), (c), and (d) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY10, are stratified as described in paragraph (b)(2) of this section.

(1) *Achievement benchmarks.* CMS uses the following scoring methodology to assess an ETC Participant's achievement score.

TABLE 1 TO § 512.370(b)(1)—ETC MODEL SCHEDULE OF PPA ACHIEVMENT BENCHMARKS BY MEASUREMENT YEAR

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the. Benchmark Year)	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.5
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0

(2) *Stratifying achievement benchmarks.* For MY3 through MY10, CMS stratifies achievement benchmarks based on the proportion of beneficiary years attributed to the aggregation group for which attributed beneficiaries are dual eligible or LIS recipients during the MY. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible

or an LIS recipient based on Medicare administrative data. CMS stratifies the achievement benchmarks into the following two strata:

(i) *Stratum 1:* 50 percent or more of attributed beneficiary years during the MY are for beneficiaries who are dual eligible or LIS recipients.

(ii) *Stratum 2:* Less than 50 percent of attributed beneficiary years during the MY are for beneficiaries who are dual eligible or LIS recipients.

(c) *Improvement scoring.* CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year to calculate the ETC Participant's improvement score, as specified in paragraph (c)(1) of this section. For MY3 through MY10, CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate for ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who are dual eligible or LIS recipients to determine whether to add the Health Equity Incentive to the ETC Participant's improvement score, as specified in paragraph (c)(2) of this section.

(1) *Improvement score calculation.* CMS uses the following scoring methodology to assess an ETC Participant's improvement score.

(i) Greater than 10 percent improvement relative to the Benchmark Year rate: 1.5 points

(ii) Greater than 5 percent improvement relative to the Benchmark Year rate: 1 point

(iii) Greater than 0 percent improvement relative to the Benchmark Year rate: 0.5 points

(iv) Less than or equal to the Benchmark Year rate: 0 points

(v) For MY3 through MY10, when calculating improvement benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, CMS adds one beneficiary month to the numerator of the home dialysis rate and adds one beneficiary month to the numerator of the transplant rate, such that the Benchmark Year rates cannot be equal to zero.

(2) *Health Equity Incentive.* CMS calculates the ETC Participant's aggregation group's home dialysis rate and transplant rate as specified in §§ 512.365(b) and 512.365(c), respectively, using only attributed beneficiary years comprised of months during the MY in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients. CMS also calculates the threshold for earning the Health Equity Incentive based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, using only attributed beneficiary years comprised of months during the Benchmark Year in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or a LIS recipient. CMS determines whether a beneficiary was dual eligible or a LIS recipient based on Medicare administrative data.

(i) The ETC Participant earns the Health Equity Incentive for the home dialysis rate improvement score if the home dialysis rate for the MY, calculated as specified in this paragraph (c)(2), is at least 2.5-percentage points higher than the home dialysis rate for the Benchmark Year, calculated as specified in this paragraph (c)(2). If the ETC Participant earns the Health Equity Incentive for the home dialysis rate improvement score, CMS adds 0.5 points to the ETC Participant's home dialysis rate improvement score, calculated as specified in paragraph (c)(1) of this section, unless the ETC Participant is ineligible to receive the Home Equity Incentive as specified in paragraph (c)(2)(iii) of this section.

(ii) The ETC Participant earns the Health Equity Incentive for the transplant rate improvement score if the home dialysis rate for the MY, calculated as specified in this paragraph (c)(2), is at least 2.5-percentage points higher than the transplant rate for the Benchmark Year, calculated as specified in this paragraph (c)(2). If the ETC Participant earns the Health Equity Incentive for the transplant rate improvement score, CMS adds 0.5 points to the ETC Participant's transplant rate improvement score, calculated as specified in paragraph (c)(1) of this section, unless the ETC Participant is ineligible to receive the Home Equity Incentive as specified in paragraph (c)(2)(iii) of this section.

(iii) An ETC Participant in an aggregation group with fewer than 11-attributed beneficiary years comprised of months in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients, during either the Benchmark Year or the MY is ineligible to earn the Health Equity Incentive.

(d) *Modality Performance Score.* (1) For MY1 and MY2, CMS calculates the ETC Participant's MPS as the higher of ETC Participant's achievement score or improvement score for the home dialysis rate, together with the higher of the ETC Participant's achievement score or improvement score for the transplant rate, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY1 and MY2:

Modality Performance Score = 2 × (*Higher of the home dialysis achievement or improvement score*) + (*Higher of the transplant achievement or improvement score*)

(2) For MY3 through MY10, CMS calculates the ETC Participant's MPS as the higher of the ETC Participant's achievement score for the home dialysis rate or the sum of the ETC Participant's improvement score for the home dialysis rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Health Equity Incentive, calculated as described in paragraph (c)(2)(i) of this section, together with the higher of the ETC Participant's achievement score for the transplant rate or the sum of the ETC Participant's improvement score for the transplant rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Heath Equity Incentive, calculated as described in paragraph (c)(2)(ii) of this section, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY3 through MY10:

Modality Performance Score = 2 × (*Higher of the home dialysis achievement or* (*home dialysis improvement score* + *Health Equity Bonus* †)) + (*Higher of the transplant achievement or* (*transplant improvement score* + *Health Equity Bonus*†))

† The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant.

■ 10. Section 512.390 is amended by revising the section heading, redesignating paragraph (b) as (c) and adding new paragraph (b).

The revision and addition read as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(b) *Data sharing with ETC Participants.* CMS shares certain beneficiary-identifiable data as described in paragraph (b)(1) of this section and certain aggregate data as described in paragraph (b)(2) of this section with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model.

(1) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with ETC Participants as follows:

(i) CMS will make available certain beneficiary-identifiable data for retrieval by ETC Participants no later than one month before the start of each PPA Period, in a form and manner specified by CMS. ETC Participants may retrieve this data at any point during the relevant PPA Period.

(ii) This beneficiary-identifiable data includes, when available, the following information for each PPA Period:

(A) The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers, dates of birth, dual eligible status, and LIS recipient status.

(B) Data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable: the number of months the beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and months following a living donor transplant.

(iii) CMS shares this beneficiary-identifiable data on the condition that the ETC Participants observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the regulations found at 45 CFR parts 160 and 164 promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended, and comply with the terms of the data sharing agreement described in paragraph (b)(1)(iv) of this section.

(iv) If an ETC Participant wishes to retrieve the beneficiary-identifiable data specified in paragraph (b)(1)(ii) of this section, the ETC Participant must complete and submit, on at least an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the ETC Participant agrees:

(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 and the requirements of the ETC 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 ETC Participant to the same terms and conditions to which the ETC 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 ETC Participant under the ETC Model.

(D) That if the ETC 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 deem the ETC Participant ineligible to retrieve beneficiary-identifiable data under paragraph (b)(1)(i) of this section for any amount of time, and the ETC Participant may be subject to additional sanctions and penalties available under the law.

(2) *Aggregate data.* CMS shares aggregate performance data with ETC Participants as follows:

(i) CMS will make available certain aggregate data for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period.

(ii) This aggregate data includes, when available, the following information for each PPA Period, de-identified in accordance with 45 CFR 164.514(b):

(A) The ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and the Health Equity Incentive.

(B) The ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, and living donor transplant rate, and the Health Equity Incentive.

(C) Information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark.

(D) The ETC Participant's MPS and PPA for the corresponding PPA Period.

* * * * *

■ 11. Section 512.397 is amended by revising the section heading and paragraph (b) and adding paragraph (c) to read as follows:

§ 512.397 ETC Model Medicare program waivers and additional flexibilities.

* * * * *

(b) CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff (as defined at § 512.310) under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The kidney disease patient education services may be furnished only by qualified staff (as defined at § 512.310).

(2) CMS waives the requirement that kidney disease patient education services are covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of starting dialysis to receive kidney disease patient education services.

(3) CMS waives the requirement that the content of kidney disease patient education services include the management of co-morbidities, including for the purpose of delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary.

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment be performed as part of a kidney disease patient education service under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed by qualified staff within one month of the final kidney disease patient education service.

(5) Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID–19 pandemic, CMS waives the geographic and site of service originating site requirements in sections 1834(m)(4)(B) and 1834(m)(4)(C) of the Act and § 410.78(b)(3) and (4) of this chapter for purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with this section, regardless of the location of the beneficiary or

qualified staff. Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID–19 pandemic, CMS also waives the requirement in section 1834(m)(2)(B) of the Act and § 414.65(b) of this chapter that CMS pay a facility fee to the originating site with respect to telehealth services furnished to a beneficiary in accordance with this section at an originating site that is not one of the locations specified in § 410.78(b)(3) of this chapter.

(c)(1) For kidney disease patient education services furnished on or after January 1, 2022, an ETC Participant may reduce or waive the 20 percent coinsurance requirement under section 1833 of the Act if all of the following conditions are satisfied:

(i) The individual or entity that furnished the kidney disease patient education services is qualified staff.

(ii) The qualified staff are not leased from or otherwise provided by an ESRD facility or related entity.

(iii) The kidney disease patient education services were furnished to a beneficiary described in § 410.48(b) or § 512.397(b)(2) who did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished.

(iv) The kidney disease patient education services were furnished in compliance with the applicable provisions of § 410.48 and § 512.397(b).

(v) The ETC Participant bears the full cost of the reduction or waiver of the 20 percent coinsurance requirement under section 1833 of the Act. The reduction or waiver of the 20 percent coinsurance requirement under section 1833 of the Act shall not be financed by a third party, including but not limited to an ESRD facility or related entity.

(2) The ETC Participant must maintain and provide the government with access to records of the following information in accordance with § 512.135(b) and (c):

(i) The identity of the qualified staff who furnished the kidney disease patient education services for which the coinsurance was reduced or waived and the date such services were furnished.

(ii) The identity of the beneficiary who received the kidney disease patient education services for which the coinsurance was reduced or waived.

(iii) Evidence that the beneficiary who received the kidney disease patient education services coinsurance waiver was eligible to receive the kidney disease patient education services under the ETC Model and did not have secondary insurance that provides cost-sharing support for kidney disease patient education services.

(iv) The amount of the kidney disease patient education coinsurance reduction or waiver provided by the ETC Participant.

(3) The Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and paragraph (c)(1) of this section.

Dated: October 28, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–23907 Filed 10–29–21; 4:15 pm]

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Part III

Department of Commerce

Publication of a Report on the Effect of Imports of Automobiles and Automobile Parts on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended; Notice

DEPARTMENT OF COMMERCE

Publication of a Report on the Effect of Imports of Automobiles and Automobile Parts on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended

AGENCY: Department of Commerce.

ACTION: Publication of a report.

SUMMARY: The Department of Commerce in this notice is publishing the Report on the Effect of Imports of Automobiles and Automobile Parts on the National Security. The report documents the findings of the Department of Commerce's investigation to determine the effects on the national security of imports of automobiles, including cars, SUVs, vans and light trucks, and automotive parts. This investigation was carried out under Section 232 of the Trade Expansion Act of 1962, as amended. All classified and business confidential information in the report was redacted before the release. This report was completed on February 17, 2019 and posted on the Bureau of Industry and Security (BIS) website on July 6, 2021. The Department of Commerce has not published the appendices to the report in this notification of report findings, but they are available online at the BIS website, along with the rest of the report (see the **ADDRESSES** section).

DATES: The report was completed on February 17, 2019. The report was posted on the BIS website on July 6, 2021.

ADDRESSES: The full report, including the appendices to the report, are available online at *https://www.bis.doc.gov/index.php/other-areas/office-of-technology-evaluation-ote/section-232-investigations.*

FOR FURTHER INFORMATION CONTACT: Brittany Caplin, Office of Public Affairs, U.S. Department of Commerce at (202) 482–4883. For more information about the section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232.*

SUPPLEMENTARY INFORMATION:

The Effect of Imports of Automobiles and Automobile Parts on the National Security

An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended

U.S. Department of Commerce

February 17, 2019

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I. Executive Summary

This report summarizes the findings of an investigation conducted by the U.S. Department of Commerce (''Department'') pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) (''Section 232''), into the effects of imports of automobiles [1] and automobile parts on the national security of the United States. In conducting this investigation, the Secretary of Commerce (''Secretary'') noted the Department's prior investigations under Section 232.[2] Consistent with those investigations, the Secretary in this investigation again determined that ''national security'' for purposes of Section 232 includes the ''general security and welfare of certain industries, beyond those necessary to

[1] For purposes of this investigation, automobiles include: Passenger vehicles, including sedans, sport utility vehicles (''SUVs''), crossover utility vehicles (''CUVs''), vans (including minivans and cargo vans), and light trucks.

[2] *See, e.g.,* Department of Commerce, Bureau of Industry and Security, *The Effect of Imports of Steel on the National Security,* Jan. 2018 (''2018 Steel Report''); Department of Commerce, Bureau of Industry and Security, *The Effect of Imports of Aluminum on the National Security,* Jan. 2018 (''2018 Aluminum Report'').

satisfy national defense requirements, that are critical to the minimum operations of the economy and government.'' [3]

On the basis of the facts considered in this investigation, the Secretary finds that the impact of excessive imports on the domestic automobile and automobile parts industry and the serious effects resulting from the consequent displacement of production in the United States is causing a ''weakening of our internal economy [that] may impair the national security'' as set forth in section 232.[4] In making this determination, the Secretary examined the increase in volume of subject imports and their effects on domestic prices, domestic production, and research and development (''R&D'') relevant to technological advancements for defense capabilities. As required by section 232(d), the Secretary also considered the impact of foreign competition on the economic welfare of the automobile and automobile parts industry in the United States. He also considered other relevant factors bearing on the state of the industry. As also required by statute, the Secretary examined the effect of imports on national defense requirements, including: U.S. production needed for such requirements; existing and anticipated availabilities of the human resources, products, raw materials, and other supplies and services essential to the national defense; the requirements for growth of such industries and such supplies and services including the investment, exploration, and development necessary to assure such growth; and the importation of goods in terms of their quantities, availabilities, characters, and use as those affect such industries and the capacity of the United States to meet national security requirements.

As also required by section 232(d), the Secretary recognized the close relation of the economic welfare of the United States to its national security; the impact of foreign competition on the economic welfare of individual domestic industries; and any substantial unemployment, decrease in revenues of government, loss of skills, or any other serious effects resulting from the displacement of any domestic products by excessive imports, without excluding other factors, in determining whether a weakening of the U.S. economy by such imports may impair national security. In particular, this report assesses whether automobiles and certain automobile parts are being imported ''in such quantities or under such circumstances as to threaten to impair the national security.'' [5] This report summarizes the findings of the Secretary.

For purposes of this report, ''U.S. producers'' and ''domestic producers'' of automobiles and automobile parts refer to both American-owned and foreign-owned producers operating in the United States.[6] Otherwise, specific reference is made to American-owned or foreign-owned producers, as appropriate.

Findings

The automotive industry has traditionally been a great engine of economic growth throughout history and, for decades, the strength of the United States' automotive manufacturing sector has directly contributed to the industrial base that provides the economic strength and technological innovation that enables our armed forces to project military power and maintain our status as a world power. Many of the most important innovations and technological advancements over the past 100 years have come from the automotive sector, and the strength of this sector drives technological advancements in the defense sector. Today, the defense sector is heavily interconnected and reliant on the automotive industry for R&D to meet current and future military requirements such as vehicle electrification, autonomous driving, hydrogen fuel cell products, advanced semiconductor utilization, radar, laser and sonar ranging, global positioning system (''GPS'') navigation, anti-lock brakes, reduction in vehicle weight (''lightweighting''), and fuel efficiency efforts. Product development in partnership between U.S. automotive manufacturers and defense agencies results in technological advancements in military aircraft, space aircraft, unmanned aerial systems, missiles, and submarines.

However, the United States' automobile industry's technological leadership in innovation is quickly diminishing. In conducting this investigation, the Secretary has found that significant import penetration over the course of the past three decades has severely weakened the U.S. automotive industry, as American-owned production of automobiles and automobile parts has been reduced by imports and the domestic manufacturing base has weakened. Overall, the share of global R&D investments in the automotive sector attributable to the United States has significantly declined and, today, the share of R&D conducted by American-owned companies is a fraction of the share conducted by foreign competitors. If production volumes continue to decline domestically, the United States' contribution to automotive R&D will further weaken and will impede the automobile industry's ability to invest in the development of technologies that are imperative to maintaining a leading edge in U.S. military capabilities.

This is especially significant for American-owned manufacturers. The Secretary notes that, in the procurement of military equipment, including military vehicles, automobiles, and automobile parts, the United States' Department of Defense (''DOD'') relies predominantly on suppliers located in the United States, both American-owned and foreign-owned. However, because in a time of national emergency, foreign-owned suppliers operating in the United States may not be reliable sources of equipment, the DOD must be able to rely on a sufficient presence of American-owned manufacturers for its military needs. In addition, due to the high cost of technological innovation in the automotive sector (and the significant revenue potential from innovative developments), manufacturers fiercely protect their technology and trade secrets in order to stay competitive, which means that American-owned firms do not have access to technology and trade secrets developed by foreign-owned firms and that, in time of war, when foreign-owned firms may decline to share their R&D with the DOD, the United States Government will not have access to all the latest developments in the industry.[7] With respect to highly-advanced technologies that have significant, cutting-edge military applications, moreover, firms tend to conduct R&D in their home countries where the potential for intellectual property spillover and theft is reduced. Thus, the U.S. military cannot depend on foreign-owned firms in the United States to access to new technologies. For

[3] Department of Commerce, Bureau of Export Administration, *The Effect of Imports of Iron Ore and Semi-Finished Steel on the National Security,* Oct. 2001 (''2001 Report'') at 5.

[4] 19 U.S.C. 1862(d).

[5] 19 U.S.C. 1862(b)(3)(A).

[6] For the purposes of this report, American-owned producers are General Motors, Ford, and Tesla, as well as Chrysler for years prior to 1998 and American Motors for 1985–1987. ''Producers'' and ''manufacturers'' are used interchangeably in this report.

[7] As much as 30 percent of industry revenue potential is attributable to new services and emerging technologies in the automotive sector. Jeff Desjardins, *The Future of Automotive Innovation,* Feb. 15, 2018, *https://www.visualcapitalist.com/future-automobile-innovation/.*

these reasons, the Secretary determines that the United States cannot rely on the presence of foreign-owned manufacturers in the United States to help meet U.S. defense requirements.

As set forth in this report, imports of automobiles and certain automobile parts are impairing the strength of American-owned firms in the automotive sector—in terms of both production and revenue needed for R&D investments—and improving the conditions for such firms is necessary to enable the development of technologies needed for our national security requirements. In conducting this investigation, the Secretary has made the following findings:

1. A Healthy U.S. Automobile and Automobile Parts Manufacturing Industry Is Necessary for U.S. Defense and National Security

The rapid application of commercial breakthroughs in automobile and automobile parts technologies is key to gaining competitive military advantages and meeting defense requirements. From new engine and powertrain technology, to lightweighting and advanced connectivity, the DOD is actively working to incorporate technologies that have been the subject of years of effort and billions of dollars of R&D by the U.S. commercial automotive industry.[8]

While the U.S. defense industrial base is dependent on the American-owned automotive sector for the development of high-tech products and capabilities, the U.S. commercial automotive industry is unable to survive solely by supplying the DOD. To this point, in 2017, 17.1 million automobiles were sold in the United States versus [TEXT REDACTED] wheeled armored vehicles. According to the DOD, it is commercial sales that generate the production volumes needed for manufacturing efficiency, the revenues needed for R&D, and the profits needed to sustain domestic automotive businesses.[9] Armored vehicles require highly sophisticated automobile parts, and it is commercial scale that allows the DOD to benefit from reduced unit costs for production of armored vehicles and cost effective access to new technology. In other words, a strong presence of American-owned companies in the United States industry allows for the development and production of highly technologically-advanced products that are essential to modern military applications for U.S. national defense.

2. Imports of Automobiles and Automobile Parts Are Impairing the Ability of the Domestic Industry To Meet National Defense Requirements

Production of automobiles in the United States has significantly weakened over the past several decades as domestic production has been replaced by an influx of low-priced imports from countries where automotive markets are protected from foreign competition. These conditions enable foreign producers to expand production in their home markets, achieve significant economies of scale and reduce prices, produce in excess of the needs of their domestic demand, export that excess production to the United States, and capture a dominant and growing share of the U.S. market.

Further, the imports of the types of automobile parts that are critical to U.S. defense needs—namely engines and engine parts, transmissions and powertrain parts, and electrical components—have significantly displaced parts manufactured in the United States and have weakened the domestic manufacturing base, including American-owned automobile parts producers, such that the automotive industry in the United States has become increasingly reliant on imported parts.

The contraction of the American-owned automotive industry, if continued, will significantly impede the United States' ability to develop technologically advanced products that are essential to our ability to maintain technological superiority to meet defense requirements and cost effective global power projection, as well as provide the necessary R&D and manufacturing base in the event of a national emergency.

3. Decline in U.S. R&D for Important Automotive Technologies Threatens To Impair U.S. National Security

This report establishes that a strong and robust American-owned R&D and manufacturing base for automobiles and automobile parts is vital to national security. However, the increase in imports of automobiles and automobile parts over three decades has put American-owned producers at a competitive disadvantage vis-à-vis their foreign-owned competitors in R&D expenditures. In 2017, R&D by American-owned manufacturers amounted to only 20 percent of global R&D spending in automobile production and only 7 percent of global R&D spending in automobile parts, lagging behind European Union (''EU'') and Japanese competitors, which together controlled 70 percent of global R&D spending in vehicle production and nearly 90 percent in automobile parts R&D. Additionally, the Asia Pacific region is now emerging as a favored destination for R&D investments. Protected foreign markets, which discriminate heavily against imports, have precluded American-owned manufacturers from offsetting their decline in the U.S. market, and thereby building R&D revenue by expanding sales through exports abroad.

Because R&D expenditures are integral to promoting long-term technological advancements in automation, electrification, and connectivity that enable cost effective power projection and maintain technological superiority for U.S. national defense, the lag in R&D expenditures by American-owned manufacturers is weakening U.S. innovation and, accordingly, the capacity of the United States to meet national security requirements. Indeed, as the U.S. military relies heavily on and adopts innovations from the commercial automotive industry, a significant decline in American-owned automotive industry investment and development also jeopardizes U.S. military leadership and its ability to fulfill America's defense requirements. Domestic conditions of competition must be improved by reducing imports so that American-owned producers are able to increase R&D expenditures and investment to assure the growth necessary to meet national defense requirements, particularly in a time of national emergency.

Conclusion and Recommendations

Based on the findings in this report, the Secretary concludes that the present quantities and circumstances of imports of automobiles and certain automobile parts, specifically engines and engine parts, transmissions and powertrain parts, and electrical components as defined in Section VIII, are ''weakening our internal economy'' and threaten to impair national security as set forth in Section 232.

As discussed throughout this report, the negative impact of imports and the resulting displacement of production for the American-owned automobile and automobile parts manufacturers are significant, and are increasing given that the U.S. automobile market is experiencing a decline in demand and contracting due to excessive imports. Defense purchases alone are not sufficient to support a robust military vehicle supply chain and R&D in key

[8] Appendix A—Letter from Secretary of Defense James Mattis to Secretary of Commerce Wilbur Ross.

[9] Consultations between Department of Commerce and Department of Defense in August 2018.

automotive technologies (such as autonomous driving, vehicle lightweighting, electrification, and connectivity) vital to meeting the needs of national defense. Hence, American-owned automobile and automobile parts manufacturers must have a robust presence in the U.S. commercial market. Moreover, innovations generated by R&D investments are necessary for manufacturers to remain competitive in both the commercial automotive sector and the defense sector. It is that innovation capability which is now at serious risk as imports continue to displace American-owned production. An American-owned automotive industry that is not competitive in the latest technologies, nor has the ability to retain a large skilled workforce and attract the next-generation workforce, will be unable to remain globally competitive and ensure that the United States maintains the ability to produce cutting-edge technologies that are essential to America's national security.

The foregoing factors explain the basis for the Secretary's determination that the ''displacement of domestic products by excessive imports''—in particular the displacement of automobiles and certain automobile parts manufactured by American-owned firms—is causing a ''weakening of our internal economy'' that ''may impair the national security.'' *See* 19 U.S.C. 1862(d). Therefore, the Secretary recommends that the President take corrective action. *See* 19 U.S.C. § 1862(c).

The Secretary recommends the following actions the President could take as possible options to remove the threatened impairment of the national security:

1. Direct further discussions and negotiations to obtain agreements that address the threatened impairment of national security. Since this investigation was initiated, there have been productive discussions that could result in positive changes for the automotive industry in the United States, and the United States has signed the USMCA. If these discussions and the USMCA result in positive changes to the U.S. automotive industry, the President could determine whether those actions address the threatened impairment of the national security found in this report.

As provided in section 232(c)(3), if appropriate agreements have not been reached in a timely manner or if a negotiated agreement is not being carried out, the President could determine that further action under section 232 is necessary.

OR

2. Impose tariffs of up to 25 percent (in addition to any existing duties) on imports of automobiles and certain automobile parts (engines and parts, transmissions and powertrain parts, and electrical components) in order to increase U.S. production of automobiles and parts to a level sufficient to generate additional revenue to increase R&D investments by American-owned (as well as foreign-owned) manufacturers in the United States. Imports under USMCA Side Letters would not be subject to the tariffs.

OR

3. Impose tariffs of up to 35 percent (in addition to any existing duties) on imports of SUVs and CUVs, which will increase domestic production and generate additional revenue to increase R&D investments by American-owned (and foreign-owned) manufacturers in the United States. The Department of Commerce would work with the U.S. Customs and Border Protection on the most appropriate means to implement this option if selected. Imports under USMCA Side Letters would not be subject to the tariffs.

Exemptions

The President may wish to consider agreements that the United States has renegotiated recently in determining whether specific countries should be exempted from the proposed tariffs based on an overriding national security interest of the United States. For example, the President should consider the Republic of South Korea for an exemption based on the recently improved agreement and strong national security relationship. The Secretary recommends that any determination to exempt a specific country should be made at the outset and a corresponding adjustment be made to the final tariffs imposed on the remaining countries. Any country exempted should be placed under a quota to ensure that producers in that country do not increase exports to the United States and to prevent transshipment through that country of automobiles and automobile parts seeking to avoid tariffs. This would ensure that overall imports of automobiles and automobile parts to the United States remain at or below the level needed to enable American-owned producers to reach levels of production sufficient to increase R&D for technologies that are important to national defense.

II. Legal Framework

A. Section 232 Requirements

Section 232 provides the Secretary with the authority to conduct investigations to determine the effect of imports of any article on the national security of the United States. It authorizes the Secretary to conduct an investigation if requested by the head of any department or agency, upon application of an interested party, or upon his own motion. *See* 19 U.S.C. 1862(b)(1)(A).

Section 232 directs the Secretary to submit to the President a report with recommendations for ''action or inaction under this section'' and requires the Secretary to advise the President if an article that is the subject of the investigation ''is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A).

Section 232(d) directs the Secretary and the President to, ''in light of the requirements of national security and without excluding other relevant factors, give consideration to domestic production needed for projected national defense requirements; the capacity of domestic industries to meet such requirements; existing and anticipated availabilities of the human resources, products, raw materials, and other supplies and services essential to the national defense; the requirements of growth of such industries and such supplies and services including the investment, exploration, and development necessary to assure such growth; and the importation of goods in terms of their quantities, availabilities, character, and use as those affect such industries and the capacity of the United States to meet national security requirements.'' *See* 19 U.S.C. § 1862(d).

Section 232(d) also directs the Secretary and the President in the administration of this section to ''further recognize the close relation of the economic welfare of the Nation to our national security, and . . . take into consideration the impact of foreign competition on the economic welfare of individual domestic industries'' and ''any substantial unemployment, decrease in revenues of government, loss of skills or investment, or other serious effects resulting from the displacement of any domestic products by excessive imports . . . [or] other factors in determining whether such weakening of our internal economy may impair the national security.'' *See* 19 U.S.C. § 1862(d).

Once an investigation has been initiated, Section 232 mandates that the

Secretary provide notice to the Secretary of Defense that such an investigation has been initiated. Section 232 (b)(2)(A) also requires the Secretary to do the following:

(1) ''consult with the Secretary of Defense regarding the methodological and policy questions raised in [the] investigation'';

(2) ''seek information and advice from, and consult with, appropriate officers of the United States''; and

(3) ''if it is appropriate and after reasonable notice, hold public hearings or otherwise afford interested parties an opportunity to present information and advice relevant to such investigation.'' [10]

As detailed in Part III of this report, each of the legal requirements set forth above has been satisfied.

In conducting the investigation, Section 232 permits the Secretary to request that the Secretary of Defense provide an assessment of the defense requirements of the article that is the subject of the investigation. *See* 19 U.S.C. 1862(b)(2)(B).

Upon completion of a Section 232 investigation, the Secretary is required to submit a report to the President no later than 270 days after the date on which the investigation was initiated. *See* 19 U.S.C. 1862(b)(3)(A). The required report must:

(1) Set forth ''the findings of such investigation with respect to the effect of the importation of such article in such quantities or under such circumstances upon the national security'';

(2) set forth, ''based on such findings, the recommendations of the Secretary for action or inaction under this section''; and

(3) ''[i]f the Secretary finds that such article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security . . . so advise the President . . .''

Id.

Department regulations require that an executive summary of the report, excluding any classified or proprietary information, be published in the **Federal Register**. Copies of the full report, excluding any classified or proprietary information, must be available for public inspection and copying. *See* 15 CFR 705.10.

Within 90 days after receiving a report in which the Secretary finds that an article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, the President shall:

(1) ''determine whether the President concurs with the finding of the Secretary;'' and

(2) ''if the President concurs, determine the nature and duration of the action that, in the judgment of the President, must be taken to adjust the imports of the article and its derivatives so that such imports will not threaten to impair the national security.'' *See* 19 U.S.C. 1862(c)(1)(A).

B. Discussion

Section 232 does not contain a definition of ''national security.'' However, both Section 232 and its implementing regulations at 15 CFR part 705 contain non-exclusive lists of factors that the Secretary must consider in evaluating the effect of imports on the national security. Congress in Section 232 explicitly provides that ''national security'' includes, but is not limited to, ''national defense'' requirements. *See* 19 U.S.C. 1862(d). In the 2001 Report, the Department determined that ''national defense'' includes both defense of the United States directly and the ''ability to project military capabilities globally.'' [11]

The Department also concluded in the 2001 Report that ''in addition to the satisfaction of national defense requirements, the term 'national security' can be interpreted more broadly to include the general security and welfare of certain industries, beyond those necessary to satisfy national defense requirements that are critical to the minimum operations of the economy and government.'' [12] This report, like the 2018 Steel Report and 2018 Aluminum Report, uses these reasonable interpretations of ''national defense'' and ''national security.'' [13]

Section 232 directs the Secretary to determine whether imports of any article are being made ''in such quantities or under such circumstances'' that those imports ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). The statutory construction makes clear that either the quantities or the circumstances, standing alone, may be sufficient to support an affirmative finding. They may also be considered together, particularly where the circumstances act to prolong or magnify the impact of the quantities being imported.

The statute does not define a threshold for when ''such quantities'' of imports are sufficient to threaten to impair the national security, nor does it define the ''circumstances'' that might qualify. Likewise, the statute does not require a finding that the quantities or circumstances are currently impairing the national security. Instead, the threshold question under Section 232 is whether the importation of such article in ''such quantities or under such circumstances'' ''*threaten* to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A) (emphasis added). This formulation strongly suggests that Congress expected that an affirmative finding under Section 232 would occur before there is actual impairment of the national security.

Additionally, in Section 232 Congress explicitly directed the Secretary to consider the ''impact of foreign competition'' and ''the displacement of any domestic products by excessive imports'' in determining whether the ''weakening of our internal economy may impair the national security,'' but made no reference to an assessment of the sources of imports. Therefore, it appears likely that Congress recognized adverse impacts might be caused by imports from allies or other reliable sources. As a result, the fact that some or all of the imports causing the harm are from reliable sources does not compel a finding that those imports do not threaten to impair national security. Indeed, as this report finds, the imports that threaten to impair the national security largely come from allies of the United States. However, as discussed further in Section VI.C, the United States cannot be certain of its ability to access intellectual property needed to maintain technological superiority and assure the ability to cost-effectively project U.S. military power when that intellectual property is under foreign ownership and control.

Section 232(d) contains a considerable list of factors for the Secretary to consider in determining if imports ''threaten to impair the national security'' [14] of the United States, and this list is mirrored in the implementing regulations. *See* 19 U.S.C. 1862(d) and 15 CFR 705.4. Congress was careful to note twice in Section 232(d) that the list it provided, while mandatory, is not exclusive.[15]

Congress broke the list of factors into two parts using two separate sentences.

[10] *See* 19 U.S.C. 1862(b)(2)(A). Department regulations (i) set forth additional authority and specific procedures for such input from interested parties, *see* 15 CFR §§ 705.7–705.8, and (ii) provide that the Secretary may vary or dispense with those procedures ''[i]n emergency situations, or when in the judgment of the Department, national security interests require it.'' *Id.* at § 705.9.

[11] 2001 Report at 5 (*supra* n. 3). *See also* 2018 Steel Report at 13; 2018 Aluminum Report at 12–13.

[12] *Id.*

[13] *See* 2018 Steel Report at 13–14; 2018 Aluminum Report at 13.

[14] 19 U.S.C. 1862(b)(3)(A).

[15] *See* 19 U.S.C. 1862(d) (''The Secretary and the President shall, in light of the requirements of national security and *without excluding other relevant factors* . . .'' This section also provides that ''other serious effects resulting from the displacement of any domestic products by excessive imports shall be considered, *without excluding other factors*. . .'') (emphasis added).

The first sentence focuses directly on ''national defense'' requirements, thus making clear that ''national defense'' is a subset of the broader term ''national security.'' The second sentence focuses on the broader economy, and expressly directs that in the administration of this section the Secretary and the President ''shall further recognize the close relation of the economic welfare of the Nation to our national security.'' *See* 19 U.S.C. 1862(d).[16]

The first sentence directs the Secretary to ''give consideration to domestic production needed for projected national defense requirements, [and] the capacity of domestic industries to meet such requirements . . .'' *See* 19 U.S.C. 1862(d). The report explains that projected national defense requirements include a viable American-owned automobile and automobile parts manufacturing industry because military vehicles rely on commercial R&D for important innovations and on domestic manufacturers for parts and production facilities. The report takes into consideration the threat of American-owned producers exiting the U.S. economy and how a reduction in domestic production impacts the ability to meet national defense requirements.

The first sentence further directs the Secretary to consider ''existing and anticipated availabilities of . . . supplies and services essential to the national defense . . .'' *See* 19 U.S.C. 1862(d). The report discusses the declining market shares of American-owned automobile producers in the United States. The report considers that imports continue to displace automobiles produced by American-owned firms in the United States, as well as automobile parts produced in the United States, and the resulting impact on R&D spending in the United States. In a time of national emergency where the United States might be dependent solely on resources within its own borders—including manufacturing, a skilled workforce, and R&D—it is essential to strengthen such capabilities in the United States so that they are fully deployable when demanded for national security.[17]

Lastly, the first sentence directs the Secretary to consider, ''the requirements of growth of such industries and such supplies and services including the investment, exploration, and development necessary to assure such growth, and the importation of goods in terms of their quantities, availabilities, character, and use as those affect such industries and the capacity of the United States to meeting national security requirements.'' *See* 19 U.S.C. 1862(d). The report details the interdependence between R&D in the automotive sector and U.S. national security.

The factors listed in the second sentence of Section 232(d) are also relevant for this investigation. Under the second sentence, the Secretary and the President are required to ''recognize the close relation of the economic welfare of the Nation to our national security, and shall take into consideration the impact of foreign competition on the economic welfare of individual domestic industries, and any substantial unemployment, decrease in revenues of government, loss of skills or investment, or other serious effects resulting from the displacement of any domestic products by excessive imports.'' The report takes into consideration the impact of excessive imports of automobiles and certain automobile parts on the American-owned automotive industry by reducing employment, weakening R&D, and causing a loss of vital skills and technological know-how in the workforce, all factors that must be considered when assessing threats to the national security from excessive imports. *See* 19 U.S.C. 1862(d).

It is these factors that the report considers which have resulted in a decline in American-owned manufacturing needed to support the research and development of technologies that maintain America's ability to cost-effectively project military power worldwide. This decline threatens the national security. The Secretary finds that this ''weakening of our internal economy,'' by a continued decline of the American-owned automobile and automobile parts manufacturing base and related R&D, ''may impair the national security.'' *See* 19 U.S.C. 1862(d).

Thus, the Secretary determines that the products listed in Section VIII are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security. *See* 19 U.S.C. 1862(b)(3)(A).

III. Investigation Process

A. Initiation of Investigation

On May 23, 2018, Secretary of Commerce, Wilbur Ross initiated an investigation to determine the effect of imported automobiles and automobile parts on national security under Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862).

Pursuant to Section 232(b)(1)(B), the Department notified the U.S. Department of Defense with a May 23, 2018 letter from Secretary Ross to the Secretary of Defense, James Mattis.[18]

On May 30, 2018, the Department published in the **Federal Register** a notice announcing the initiation of this investigation to determine the effect of imports of automobiles and automobile parts on the national security. The notice also announced the opening of the public comment period as well as a public hearing to be held on July 19 and July 20, 2018.[19]

B. Public Comments

On May 30, 2018, the Department invited interested parties to submit written comments, opinions, data, information, or advice relevant to the criteria listed in Section 705.4 of the National Security Industrial Base Regulations (15 CFR 705.4) as they affect the requirements of national security, including the following:

a. The quantity and nature of imports of automobiles, including cars, SUVs, vans and light trucks, and automotive parts and other circumstances related to the importation of automobiles and automotive parts;

b. Domestic production needed for projected national defense requirements;

c. Domestic production and productive capacity needed for automobiles and automotive parts to meet projected national defense requirements;

d. The existing and anticipated availability of human resources, products, raw materials,

[16] *See also* 50 U.S.C. 4502(a)(7), in which Congress explicitly recognized ''much of the industrial capacity that is relied upon by the United States Government for military production and other national defense purposes is deeply and directly influenced by (A) the overall competitiveness of the industrial economy of the United States; and (B) the ability of industries in the United States, in general, to produce internationally competitive products and operate profitably while maintaining adequate research and development to preserve competitiveness with respect to military and civilian production . . .''

[17] *See also* 50 U.S.C. 4502(a)(8) recognizing that ''the inability of industries in the United States, especially smaller subcontractors and suppliers, to provide vital parts and components and other materials would impair the ability to sustain the Armed Forces of the United States in combat for longer than a short period.''

[18] 19 U.S.C. 1862(b)(1)(B). *See* Appendix A: Section 232 Investigation Notification Letter to Secretary of Defense James Mattis, (May 23, 2018).

[19] *See* Appendix B for Department of Commerce, ''*Notice of Request for Public Comments and Public Hearing on Section 232 National Security Investigation of Imports of Automobiles, including Cars, SUVs, Vans and Light Trucks, and Automotive Parts,*'' 83 FR 24,736–24,737 (May 30, 2018). Also included in Appendix B is the subsequent Department of Commerce Notice, ''*Public Hearing on Section 232 National Security Investigation of Imports of Automobiles, Including Cars, SUVs, Vans and Light Trucks, and Automotive Parts; Change of Date for the Public Hearing,*'' 83 FR 32,833 (Jul. 16, 2018).

production equipment, and facilities to produce automobiles and automotive parts;

e. The growth requirements of the automobiles and automotive parts industry to meet national defense requirements and/or requirements to assure such growth, particularly with respect to investment and research and development;

f. The impact of foreign competition on the economic welfare of the U.S. automobiles and automotive parts industry;

g. The displacement of any domestic automobiles and automotive parts causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills and productive capacity, or other serious effects;

h. Relevant factors that are causing or will cause a weakening of our national economy;

i. The extent to which innovation in new automotive technologies is necessary to meet projected national defense requirements;

j. Whether and, if so, how the analysis of the above factors changes when U.S. production by majority U.S.-owned firms is considered separately from U.S. production by majority foreign-owned firms; and

k. Any other relevant factors.[20]

The public comment period ended on June 29, 2018, and public rebuttal comment period ended on July 13, 2018. The Department received 2,356 written public comment submissions concerning this investigation. All public comments were carefully reviewed and factored into the investigation process. A listing of all public comments is available at the U.S. Government's *Regulations.gov* website specific to this investigation: *https://www.regulations.gov/docket?D=DOC-2018-0002.*

C. Public Hearing

The Department held a public hearing to collect additional information concerning this investigation in Washington, DC on July 19, 2018. The second day of the hearing, originally scheduled for July 20, was cancelled because all parties who wished to participate could be accommodated in one day. The Department heard testimony from 44 witnesses at the hearing. The complete hearing transcript is included in Appendix C.

D. Interagency Consultation

In addition to the required notification provided by the May 23, 2018 letter from Secretary Ross to Secretary Mattis,[21] the Department carried out the consultations required under Section 232(b)(2).[22] Department staff consulted with counterparts at the DOD and U.S. Customs and Border Protection regarding any methodological and policy questions that arose during the investigation.[23]

Secretary Mattis also communicated the views of the DOD in a November 15, 2018 letter to Secretary Ross.[24] In that letter, Secretary Mattis noted that the Department of Commerce had consulted with the DOD and stressed the importance of the automobile sector and related technologies to U.S. defense requirements and national security needs. Specifically, Secretary Mattis stated:

> A healthy U.S. automotive sector supports the manufacturing ecosystem vital to our national defense industrial base. As noted in the National Defense Strategy, ''new commercial technology will change society and, ultimately, the character of war.'' Therefore, U.S. automotive sector leadership in emerging technologies, like autonomous systems, is also critical for continued Department of Defense modernization.[25]

E. U.S. Producers' Survey Responses

On June 29, 2018 and on July 25, 2018, respectively, the Department issued industry surveys to U.S. automobile producers and U.S. armored vehicle producers pursuant to 50 U.S.C. 4555. Information sought included, *inter alia,* facilities and production data, joint venture data, trade flows, supply chain data, sales and demand data, employment information, conditions of competition, R&D information, and government and defense activities. The principal goal of the survey was to assist the Department in determining whether automobiles and automobile parts are being imported into the United States in such quantities or under such circumstances as to threaten to impair national security. The resulting aggregate data have given the Department detailed industry information that is otherwise not publicly available and was needed to effectively conduct its analysis for this investigation.

Response to the Department's survey is required by law (50 U.S.C. 4555). Information furnished in the survey responses has been deemed confidential and will not be published or disclosed except in accordance with Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. 4555). Section 705 prohibits the publication or disclosure of this information unless the President determines that the withholding of such information is contrary to the interest of the national defense. Information will not be shared with any non-government entity other than in aggregate form. The information is protected pursuant to the appropriate exemptions from disclosure under the Freedom of Information Act (''FOIA''), should it be the subject of a FOIA request.

From June 29, 2018 to September 7, 2018, the following [TEXT REDACTED] companies responded to the Department's questionnaires:

[TEXT REDACTED]

IV. Product Scope of the Investigation

The scope of this investigation includes passenger vehicles, including sedans, sport utility vehicles (''SUVs''), crossover utility vehicles (''CUVs''), and vans (including minivans and cargo vans); light trucks (collectively ''automobiles''); and wheeled armored and tactical vehicles used for U.S. military applications. The scope also includes all categories of automobile parts used in automobiles and armored vehicles, which are defined at multiple points throughout the U.S. Harmonized System (''HS''). A complete listing of automobile and automobile parts codes included in this investigation is provided in Appendix D. As detailed in this report, the Secretary finds that imports of automobiles and imports of engines, engine parts, transmissions, powertrain parts, and electrical components have displaced and threaten further displacement of domestic production and thereby threaten to impair the national security as set out in Section 232. For the purposes of this report, American-owned automobile producers are General Motors (''GM''), Ford, and Tesla. Prior to 1998, Chrysler was also American-owned. During 1985–1987, American Motors was American-owned.

V. Background on the Industry

A. Global Competitiveness of U.S. Automobile Producers

The U.S. automotive industry has been one of the most powerful forces driving the U.S. economy. Automobile manufacturing and associated services industries employed 4.2 million workers in 2017, amounting to 3 percent of total private sector employment. Of these jobs, 953,000 were in automobile, automotive body, and automobile parts manufacturing and an additional 3.3 million in service industries such as

[20] *Id.* In response to requests from interested parties, the Department issued a *Notice of Request for Public Comments and Public Hearing; Extension of Comment Period,* 83 FR 28801 (Jun. 21, 2018), extending the due date for comments to June 29, 2018 and rebuttal comments to July 13, 2018.

[21] *See* Appendix A.

[22] 19 U.S.C. 1862(b)(2).

[23] *Id.*

[24] *See* Appendix A: Letter from Secretary of Defense James Mattis to Secretary Ross conveying DOD views on Section 232 investigation on imports of automobiles and automobile parts, Nov. 15, 2018.

[25] *Id.*

dealerships, repair shops, and automobile parts stores.[26]

Global competition has greatly changed the industry over the years. In the 1960s and 1970s, U.S. automobile producers enjoyed a dominant position globally, as 48 percent of global automobile production occurred in the United States, and all of those producers were American-owned firms.[27] The United States' competitive position in the global marketplace did not last, however, as foreign competitors aggressively penetrated the global market and captured a significant portion of global market share. By 1985, automobile production in the United States as a percentage of global automobile production declined to 26 percent, then to 18 percent in 2005, and to 12 percent in 2017 as shown in Figure 1A.[28] In 2017, American-owned manufacturers within the United States and abroad held only 12 percent of the global market which, as shown in Figure 1B, represents a significant decline from the 36 percent of global market share held by American-owned manufacturers in 1995. The decline in global market share reflects the rise of foreign-owned producers and the weakening of the U.S. automotive manufacturing base.

The 2008–2009 worldwide economic downturn exacerbated the contraction of U.S. market share in the global automotive sector, and in 2009 U.S. automobile production in the aggregate (by American-owned and foreign-owned firms) declined to 5.7 million units, which is just nine percent of global production.[29] Although global production rebounded from 72.8 million units in 2007 to 96.2 million units in 2017,[30] the rise in production volume was largely attributed to China's dramatic rise, growing from less than 8.9 million units in 2007 to 29.0 million units in 2017.[31] China became the number one automobile producing country in 2009, and in 2017 produced over 25 percent of the world's supply of automobiles.[32] The EU, Japan, South Korea, Canada, and Mexico are also major producers of automobiles, and are the top sources of automobile imports into the United States. Manufacturers in the United States, Japan, and the EU moved some automobile production for the North and South American markets to Mexico, leading to an increase in production there. Despite significant automobile production in Canada and Mexico, there are no Canadian- or Mexican-owned automobile producers in those counties.

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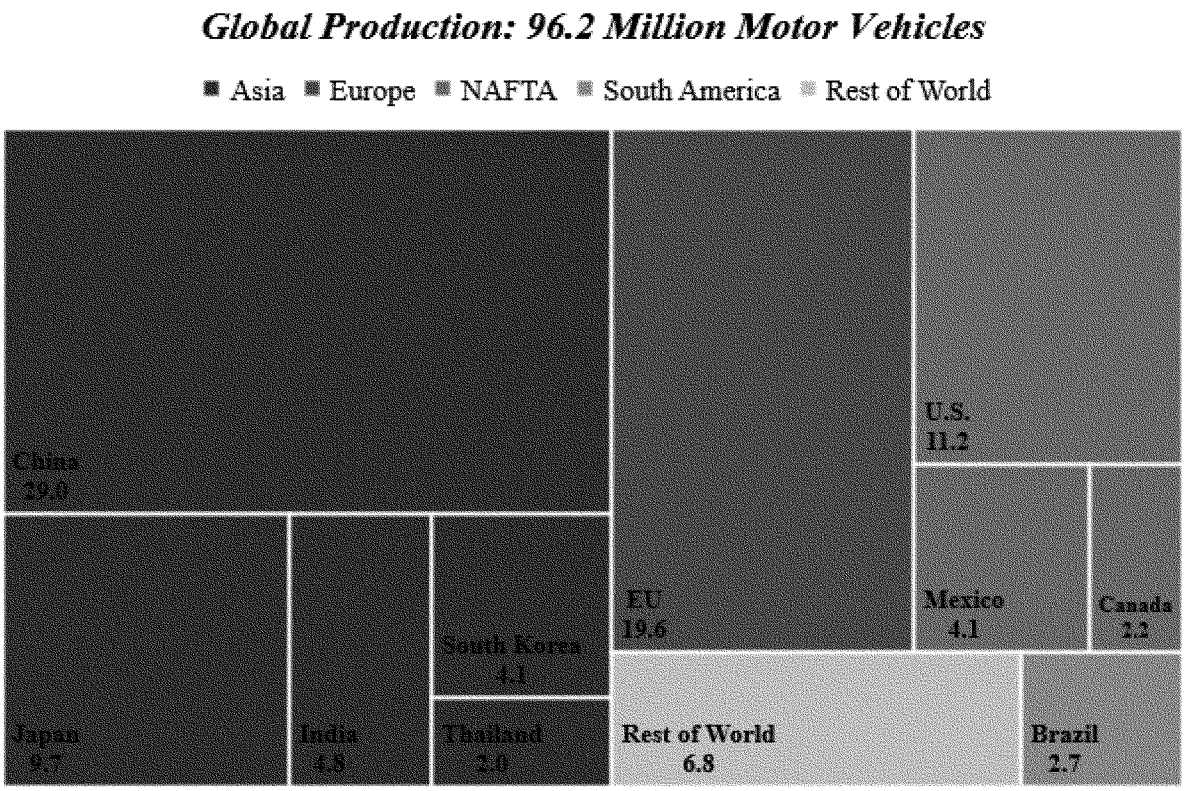
Figure 1A: 2017 Global Automobile Production by Country



Source: Wards Intelligence InfoBank. (Values shown in millions of units. Excludes small countries that do not report to Wards. Includes medium and heavy duty trucks.)

[26] Department of Labor, Bureau of Labor Statistics, *Automotive Industry: Employment, Earnings, and Hours, https://www.bls.gov/iag/tgs/iagauto.htm.*

[27] Wards Intelligence InfoBank.

[28] *Id.* (These figures include foreign-owned manufacturers in the United States.)

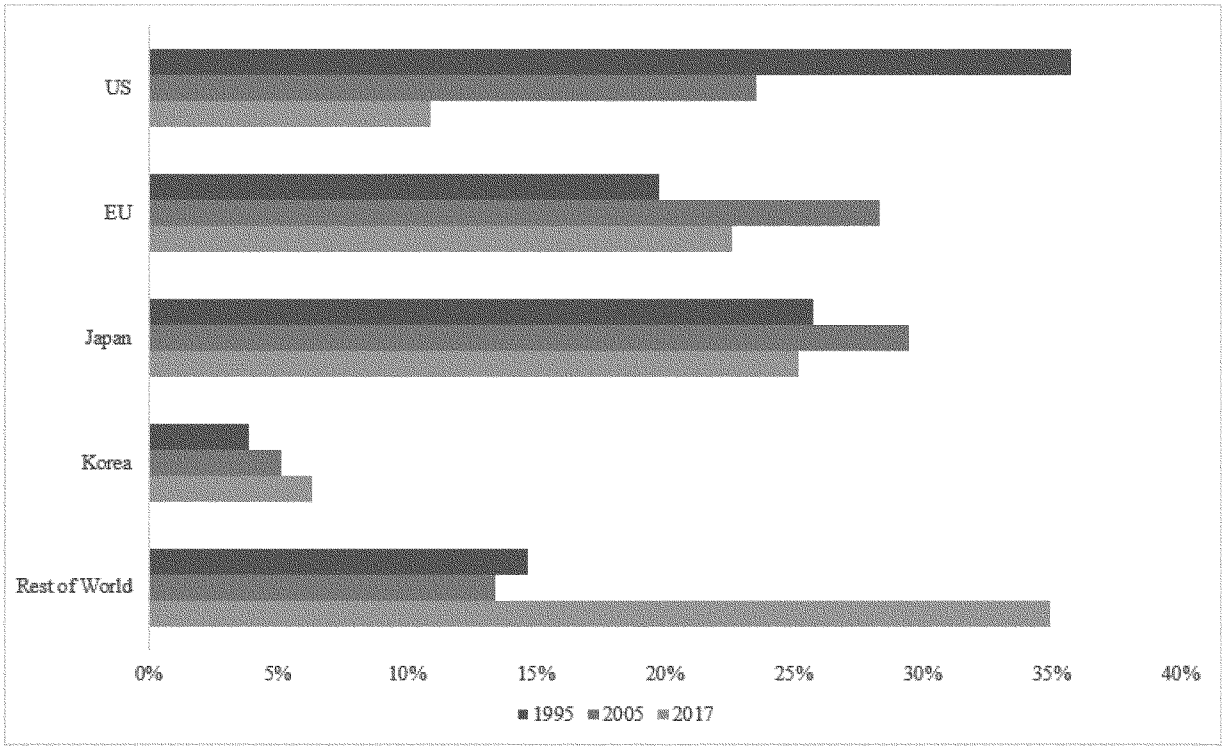
[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

Figure 1B: Share of Global Production, by Ownership, Major Producers



Source: Wards Intelligence InfoBank. (1995 statistics represent the earliest-available data on global production by country in which the producer is headquartered; data include medium and heavy-duty vehicles. In the case of a joint venture, the ownership is attributed to the majority partner.)

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Globally, the four largest automobile producers in 2017 were GM, Toyota, Volkswagen, and Ford, and each manufacturer produces and sells a significant percentage of its automobiles in its home country. Further, because global automobile production is regionally focused, the world's leading manufacturers also produce automobiles in foreign markets to supply local customers. As summarized in Table 1 below, 23 percent and 39 percent of automobiles produced by American-owned manufacturers GM and Ford, respectively, in 2017 were made in the United States. Similarly, 35 percent of automobiles produced by Toyota and 18 percent produced by Volkswagen were made in their home markets.

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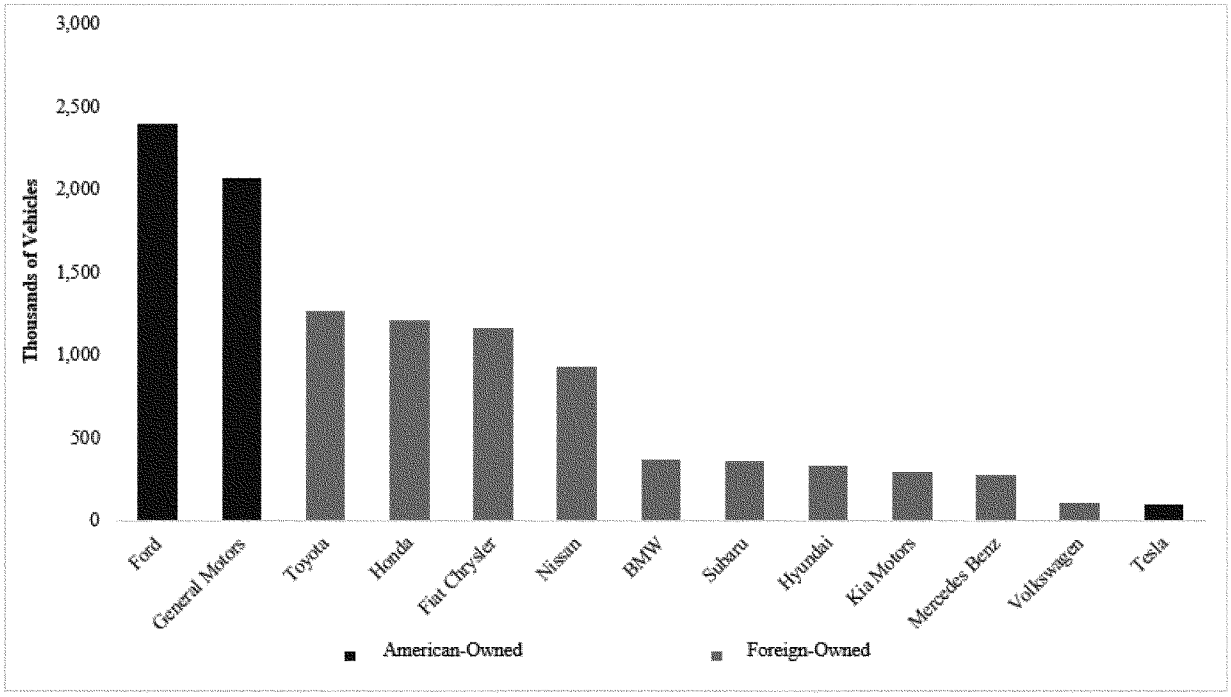
Table 1: 2017 Share of Automobiles Produced in Home Market

	GM	Toyota	Volkswagen	Ford
Number Produced Globally (millions)	8.90	8.89	8.46	6.11
Share Produced in Home Market	23%	35%	18%	39%

Source: Wards Intelligence InfoBank (excludes Africa). Volkswagen's home market is Germany, and Toyota's home market is Japan.

The automobile industry in the United States consists of 14 major manufacturers: American-owned GM, Ford, and Tesla, and 11 ''transplant'' manufacturers, *i.e.,* manufacturing facilities that are ultimately owned by corporations headquartered abroad.[33]

Figure 2: 2017 Automobile Production in the United States, by Manufacturer



Source: Wards Intelligence InfoBank. Data for Volvo, which began producing automobiles in the United States in 2018, is not yet available.

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Three major trends in automobile manufacturing are (1) continuing efforts to cut costs to remain globally competitive, (2) improving technological advancements in design and materials used to decrease vehicle weight (''lightweighting'') and enhance fuel efficiency, and (3) developing advanced technologies needed for increased vehicle connectivity, electrification and autonomous driving. Manufacturers are increasingly cutting costs through automation and by relocating production to less expensive regions. The tariff reductions achieved in 1994 through the North American Free Trade Agreement (''NAFTA'') incentivized offshoring of automobile and automobile parts production to Mexico where input costs, particularly labor, were significantly cheaper.[34]

B. U.S. Automobile Producers' Transition From Vertical Integration to Outsourcing Automobile Parts Production

The automotive industry responded to declining profits and structural and technological changes in the late 1980s by switching from a vertically-integrated supply structure to a model that increasingly sourced automobile parts from independent suppliers serving multiple customers. This global shift was especially dramatic in the United States, where automobile producers were under tremendous pressure to become more efficient and reduce costs to compete with imports. Producers opted to purchase large modules and subassembly systems ready for installation on their assembly lines, rather than assemble thousands of individual parts as before. In the United States, union wages were lower for component companies than for original equipment manufacturers (''OEMs''). Over time, U.S. automobile producers also shifted to negotiating large long-term contracts with a select group of tier-1 suppliers.[35] As parts suppliers became separate entities from the automobile producers, the parts suppliers were forced to assume more responsibility for R&D and the design of innovative modules and systems and they began to maintain large inventories of various automobile parts.[36] The percentage of parts that independent suppliers contribute to a vehicle has grown from 40–50 percent in the early 1990s to over 70 percent today.[37]

[33] Wards Intelligence InfoBank. Volvo began production at its Charleston, South Carolina plant in October 2018 and is therefore not included in Figure 2.

[34] *See* Section V, Part C.

[35] A tier-1 supplier provides components directly to the OEM.

[36] Thomas Klier and James Rubenstein, *Who Really Made Your Car,* The Federal Reserve Bank of Chicago, Chicago Fed Letter, No. 255a, Oct. 2008, *https://www.chicagofed.org/~/media/publications/chicago-fed-letter/2008/cfloctober2008-255a-pdf.pdf.*

[37] Patrick McGee, *Carmakers Face Threat from New Drivers of Profit,* Financial Times, Aug. 8, 2017, *https://www.ft.com/content/40065b50-715e-11e7-93ff-99f383b09ff9.*

The shift away from the vertical integration of automobile and automobile parts production is also essential to understanding the nature of automotive industry employment. The automotive supply chain has become the backbone of the automobile assembly industry, employing more people than the automobile producers. In 1990, 271,400 automobile manufacturing employees and 653,000 automobile parts employees produced 9.5 million vehicles in the United States. After a decade of record high automobile production, beginning in 2001 automobile manufacturing employment declined each year to a low of 146,400 workers in 2009. For automobile parts manufacturing, employees increased by 29 percent to a high of 839,500 in 2000 before falling to a low of 413,700 workers in 2009. While employment overall rebounded somewhat after 2009, in 2017 workers in both the automobile sector (212,000 employees) and automobile parts sector (586,300 employees) remain 29 percent below their 2000 levels, despite record demand.[38] Many of these jobs moved offshore as a result of import competition in the United States and lower labor costs available abroad.[39]

C. NAFTA and the Rise of Automobile and Automobile Parts Production in Mexico Instead of the United States

The contraction of the U.S. automotive industry has been ongoing for decades, but the contraction became more dramatic after NAFTA went into effect and caused a significant portion of the U.S. industry to shift production to Mexico. Prior to NAFTA, Mexico had in place a restrictive decree that limited automotive trade. NAFTA, however, expanded to Mexico the existing integration of the U.S. and Canadian automotive manufacturing supply chain created under the Canada-United States Automotive Products Agreement (signed in 1965) and the U.S./Canada Free Trade Agreement (signed in 1989). NAFTA's elimination of customs tariffs allowed automobile producers and automobile parts suppliers to optimize operational structures by relocating assembly operations and supply chain manufacturing to Mexico the most cost competitive location within North America. The results of the shift in supply chain are dramatic. Since NAFTA's entry into force, the value of U.S. imports of automobile parts from Mexico increased by 652 percent, and the value of automobile imports from Mexico increased by over 1,000 percent.[40]

1. The Rise of Automobile Assembly in Mexico and Offshoring of Automobile Plants

Mexico's ability to compete for new North American automotive investments under NAFTA stemmed primarily from the country's relatively lower labor costs. Automobile assembly compensation had been approximately 80 percent lower in Mexico than in the United States, and labor represented a sizeable share of the production cost for automobiles.[41] For example, from 2008 to 2013, the average hourly wage in Mexico was $5.89 ($US, nominal) for the automobile sector. These wages were slightly more than one-seventh of the comparable wage in the United States.[42] In 2016, the hourly wage for workers in the automobile sector was $4.65 in Mexico compared to $40.17 in the United States.[43] In Mexico, dollar equivalent wages decreased because the currency depreciated sharply in comparison to the U.S. dollar.[44] This large disparity in wages resulted in significant cost savings to manufacturers. One analysis estimated that assembling an automobile in Mexico resulted in an average cost savings of $1,200 for an automobile sold in the United States and $4,300 for an automobile sold in Europe.[45] Lower Mexican wages, coupled with labor productivity that is comparable to workers in the United States, influenced corporate decisions to increase automobile assembly in Mexico.

In fact, between 2011 and 2016, nine of the 11 announced new automobile assembly plants in North America were built in Mexico,[46] while the number of facilities in the United States declined. The large rise in Mexican assembly investment is relevant because 80 percent of Mexican vehicle production is exported to the United States.[47] As shown in Table 2, in 1985, there were 65 automobile assembly plants in the United States and 12 plants in Canada, but only nine in Mexico. As of 2017, the number of automobile assembly plants in the United States declined by 30 percent to 46 plants, while the number of Mexican automobile assembly plants doubled to 18. The number of Canadian automobile assembly plants declined only modestly from 12 assembly plants to 11 during the same period.[48]

Table 2: Automobile Assembly Plants in North America, 1985-2017

	1985	1990	1995	2000	2005	2010	2015	2017
Canada	12	17	14	14	11	11	10	11
Mexico	9	8	14	13	12	12	15	18
United States	65	62	63	62	66	48	47	46

Source: Wards Intelligence InfoBank (includes foreign-owned production in each country).

[38] Department of Labor, Bureau of Labor Statistics, Employees for Motor Vehicles (NAICS 3361) and Motor Vehicle Parts (3363) industries, *https://www.bls.gov/iag/tgs/iagauto.htm.*

[39] Thomas H. Klier and James M. Rubenstein, *Imports of Intermediate Parts in the Auto Industry—A Case Study,* November 6–7, 2009, *https://upjohn.org/measurement/klier-rubenstein-final.pdf* at 4.

[40] Department of Commerce, Census Bureau, International Trade Management Division. Retrieved from Trade Policy Information System (TPIS) Database: USHS IMPORTS, Revised Statistics for 1989–2017.

[41] Bernard Swiecki and Debbie Maranger Menk, *The Growing Role of Mexico in the North American Automotive Industry,* Center for Automotive Research, July 2016, *http://www.cargroup.org/wp-content/uploads/2017/02/The-Growing-Role-of-Mexico-in-the-North-American-Automotive-Industry-Trends-Drivers-and-Forecasts.pdf.*

[42] International Labor Comparisons, The Conference Board, *https://www.conference-board.org/ilcprogram.*

[43] *Id.* These data are calculated by the Conference Board's International Labor Comparisons (ILC) program using the same concepts and methodology as those developed by the Bureau of Labor and Statistics. Compensation costs relate to all employees in manufacturing and include (1) direct pay and (2) employer social insurance expenditures and labor-related taxes.

[44] Board of Governors of the Federal Reserve System, Foreign Exchange Rates—G.5A Annual

[45] Swiecki and Menk, *The Growing Role of Mexico in the North American Automotive Industry, supra.*

[46] *Id.*

[47] *Id.*

[48] Wards Intelligence InfoBank.

In addition to low production costs, low tariffs on Mexican automobile exports due to the broad reach of Mexico's numerous Free Trade Agreements (''FTAs'') made it possible for the country to emerge as a prime manufacturing and export base not only within North America, but globally as well. Exports from Mexico to 46 countries are exempt from automobile tariffs, including the 10 percent tariff the EU applies to imported passenger vehicles.[49] The domestic Mexican market for new automobiles is relatively small, less than 10 percent the size of the U.S. automobile market, and the growth of automobile production in Mexico correspondingly includes a large share of automobiles manufactured for export.[50] Between 1990 and 2017, the percentage of automobiles manufactured in Mexico for export increased from 34 percent to 84 percent.[51] Since 2010, moreover, automobile manufacturers announced more than $24 billion in investments in Mexico, including more than $6.5 billion in investments from Japanese firms, more than $5.7 billion in investments from German firms, and more than $1.1 billion from South Korean firms.[52]

The rise of Mexico as a major automobile producer has contributed to the gradual decline of U.S. automobile production, as the U.S.-made share of automobile production in North America, which was 78 percent in 1990, dropped to 64 percent in 2017, as shown in Table 3.[53] Some analysts expect the share of production in the United States to drop to below 60 percent by 2020 under the existing NAFTA rules.[54]

Although Canada's share of North American production remained relatively stable, going from 14 percent in 1985 to 13 percent in 2017,[55] Canada's production volume is expected to rise in the near-term as a result of Canada's 2016 Comprehensive Economic and Trade Agreement (''CETA'') with the EU, which immediately eliminated the EU's tariffs on Canada-made automobile parts (which had ranged up to 4.5 percent) and phases out tariffs on automobiles over seven years.[56]

Table 3: Share of North American Automobile Production

	1985	1990	1995	2000	2005	2010	2015	2017
Canada	13.95	15.55	15.87	16.99	16.65	17.32	13.01	12.80
Mexico	3.16	6.54	6.15	10.89	10.20	18.89	19.42	22.99
United States	82.89	77.91	77.98	72.13	73.15	63.79	67.58	64.20

Source: Wards Intelligence InfoBank (includes foreign-owned production).

2. Offshoring of Automobile Parts

With the transition away from vertical integration in the global automotive industry, automobile parts manufacturers have been under systematic pressure from automobile producers to lower prices. In response, suppliers explored different ways to cut costs and, soon after NAFTA's implementation, they began supplementing and eventually replacing significant domestic production with ''near shore'' production in Mexico. Consequently, U.S. imports of automobile parts from Mexico increased rapidly. In 1990, U.S. imports of automobile parts from Mexico were valued at $4.5 billion, accounting for 14 percent of total U.S. automobile parts imports. By 2004 (a decade into NAFTA) U.S. imports of automobile parts from Mexico rose to $23.4 billion, accounting for almost 30 percent of total automobile parts imports.[57] And in 2017, U.S. imports of automobile parts from Mexico reached $55.3 billion in total, accounting for 37 percent of overall U.S. imports of automobile parts. Eleven percent of U.S. automobile parts imports in 2017 came from Canada, and imports from Canada and Mexico together accounted for 48 percent of total U.S. imports in 2017. Of the remaining 52 percent of U.S. automobile parts imports in 2017, 13 percent originated from the EU and 36 percent were imported from Asia, including Japan, South Korea, and China.[58]

According to ProMexico, an export promotion division of the Government of Mexico, close to 90 of the global 100 tier-1 parts suppliers have operations in Mexico.[59] Although some of the investments are for low value, labor-intensive goods like wire harnesses, Mexico has also attracted automotive supplier investments for higher value goods. For example, Mexico has expanded its powertrain production numbers over the past several years and, from 2012 through 2015 alone, engine production in Mexico has increased by over 31 percent, from 2.8 million to 3.7 million engines, and is estimated to have grown to 4.2 million units in 2018.[60]

Furthermore, automotive producers have increasingly chosen Mexico as a place to locate R&D centers.[61] GM, Ford, Toyota, Volkswagen, Nissan, and numerous automobile parts companies already conduct significant R&D activity in Mexico. U.S. industry considers university graduates in Mexico to be just as skilled for R&D work as graduates in the United States.[62] With the tendency of automobile producers to locate R&D facilities near assembly plants, Mexico is expected to become a growing market for engineering jobs and an alternative market to the United States. As R&D and its related skilled workforce shifts from the United States to Mexico, the loss of specialized skills and production know-how within the United States impedes the ability of American-owned manufacturers to access a skilled workforce and advance technologies that are critical for maintaining America's ability to project power globally and respond in a national emergency.

[49] World Trade Organization, *Tariff Download Facility, http://tariffdata.wto.org/.*

[50] Department of Commerce, Census Bureau; Wards Intelligence InfoBank.

[51] Swiecki and Menk, *The Growing Role of Mexico in the North American Automotive Industry, supra.*

[52] *Id.*

[53] Wards Intelligence InfoBank.

[54] Swiecki and Menk, *The Growing Role of Mexico in the North American Automotive Industry, supra.*

[55] Wards Intelligence InfoBank.

[56] Sara Lewis, *Canadian, EU Auto Industries Welcome Trade Pact,* WardsAuto, Feb. 24, 2017, *https://www.wardsauto.com/industry/canadian-eu-auto-industries-welcome-trade-pact.*

[57] Department of Commerce, Census Bureau.

[58] *Id.*

[59] Swiecki and Menk, *The Growing Role of Mexico in the North American Automotive Industry, supra.*

[60] *Id.*

[61] *Id.*

[62] *Id.*

VI. Analysis

A. Present Import Quantities of Automobiles Have Weakened the American-Owned Automotive Industry

In the U.S. automobile sector, there is substantial evidence that imports have weakened the domestic industry and are causing the American-owned segment of the industry to contract. Foreign-owned automobile producers in the United States are able to offset the economic effects of a contraction in the U.S. market by maintaining significant sales volumes in their protected home markets. However, as explained in Appendix F, under the present trade regime, American-owned manufacturers are unable to meaningfully penetrate those same protected foreign markets to offset their shrinking sales in the United States. In fact, as shown in Figure 1B above, from 1995 to 2017 American-owned automobile producers' share of the global automotive market contracted by 24 percentage points, from 36 percent to 12 percent, while EU automobile producers' share grew from 20 percent to 23 percent and Japanese automobile producers' share stayed relatively steady at 26 percent and 24 percent during the same period. Clearly, American-owned manufacturers are trailing behind their foreign-owned competitors in the global market, which impacts their sales revenue and, hence, R&D investments in technologies that are integral to maintaining America's technological advantage in military applications. Consequently, America's ability to cost-effectively project power globally is also trailing behind. As set forth in Section VI.C, the U.S. military depends heavily on innovation in the commercial automotive sector, and in particular will depend on American-owned manufacturers' innovation capabilities in time of war. The following sections analyze the impact of imports on the U.S. automotive market, the weakened competitive position of American-owned producers, and the consequent threat to the impairment of national security.[63]

1. U.S. Automobile Production Volume Has Eroded Over Three Decades Due to Imports

The strength of the U.S. automotive industry has weakened since 1985. Evidence establishes that purchasers have increasingly shifted away from domestically-produced automobiles to imported vehicles, and data provided in Figure 3 show that from 1985 to 2017 demand for automobiles in the U.S. market grew by 11 percent, but total domestic production by both American- and foreign-owned firms declined by 4 percent. More specifically, U.S. demand for automobiles grew from 15.4 million units in 1985 to 17.1 million units in 2017, while production by domestic automobile producers declined from 11.4 million units in 1985 to 10.9 million units in 2017.[64] Over the same period, U.S. imports of automobiles nearly doubled from 4.6 million units to 8.3 million units.[65] Expressed as a percentage of market share (an indicator of competitive strength), domestic producers' share of the U.S. market declined over this 32-year period from 70 percent of overall U.S. demand in 1985 to 52 percent in 2017.[66] Production by domestic manufacturers of automobiles held steady in 2018.[67]

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[63] *See* 19 U.S.C. 1862(b) and (d).

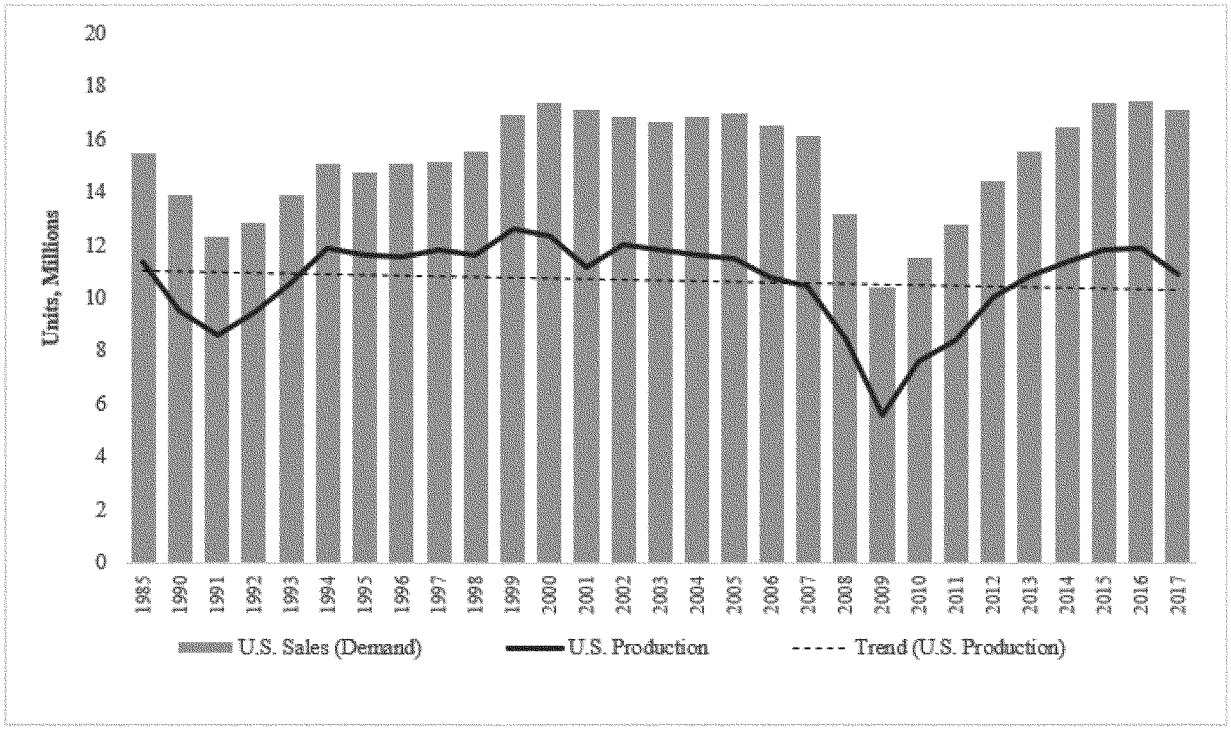
[64] According to Wards Intelligence InfoBank, U.S. automobile production peaked at 12.6 million units in 1999, but subsequently plummeted to 5.6 million units in 2009 as a result of the economic recession. Although production ultimately recovered to 11.9 million units in 2016, by 2017 production again slipped to 10.9 million units.

[65] Department of Commerce, Census Bureau.

[66] Wards Intelligence InfoBank and Department of Commerce, Census Bureau. Domestic producers' market share is calculated as (domestic sales *minus* imports) *divided by* domestic sales.

[67] Wards Intelligence InfoBank.

Figure 3: U.S. Automobile Production Relative to Demand



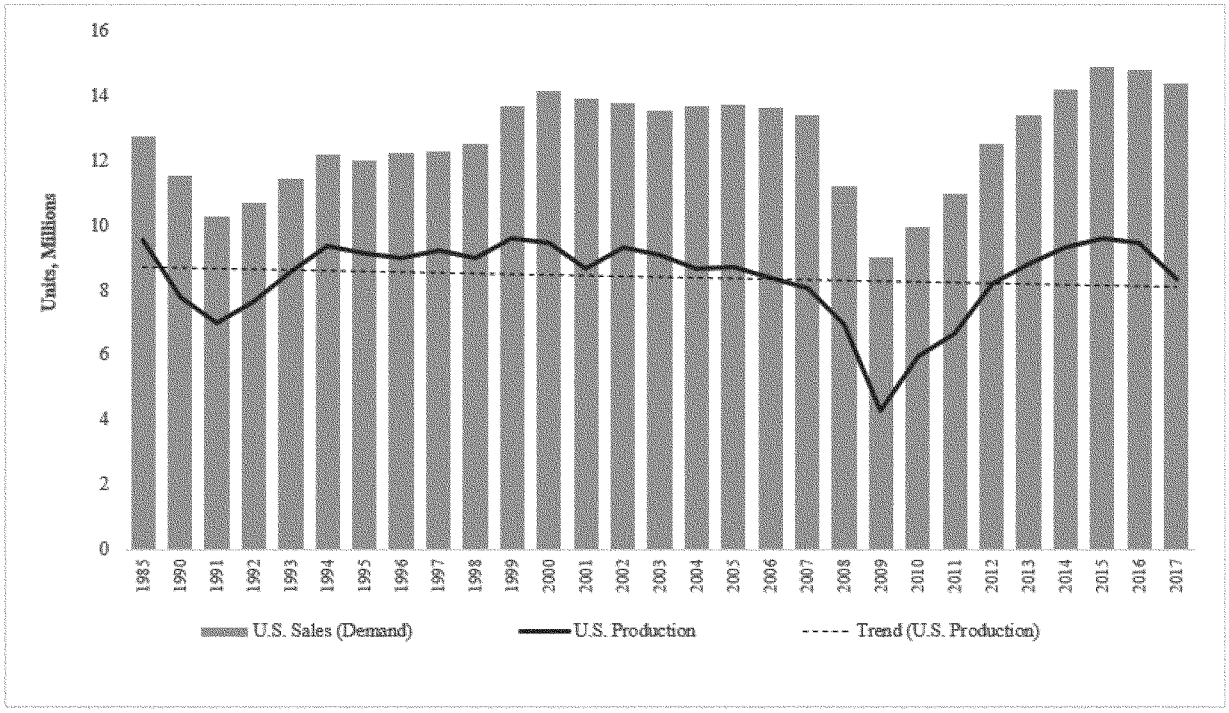
Source: Wards Intelligence InfoBank.

When disaggregated into passenger vehicles (sedans, SUVs, CUVs, and vans) and light trucks, it becomes clear that the decline in U.S. production has been concentrated in the passenger vehicle segment. Figure 4 demonstrates that, for passenger vehicles overall, U.S. demand increased by 13 percent, from 12.8 million passenger vehicles in 1985 to 14.4 million passenger vehicles in 2017, while U.S. production decreased by 12.9 percent over the same period, from 9.6 million passenger vehicles to 8.4 million passenger vehicles. Of the 8.4 million passenger vehicles produced in the United States in 2017, approximately 6.8 million were sold in the United States in 2017.[68] Expressed as a percentage of market share, domestic producers' share of U.S. passenger vehicle sales declined from 72 percent in 1985 to 48 percent in 2017.[69] Section VI.A.3 explains that this contraction is due, in large part, to displacement by passenger vehicle imports.

[68] Wards Intelligence InfoBank and Department of Commerce, Census Bureau.

[69] Wards Intelligence InfoBank.

Figure 4: U.S. Passenger Vehicle Production Relative to Demand



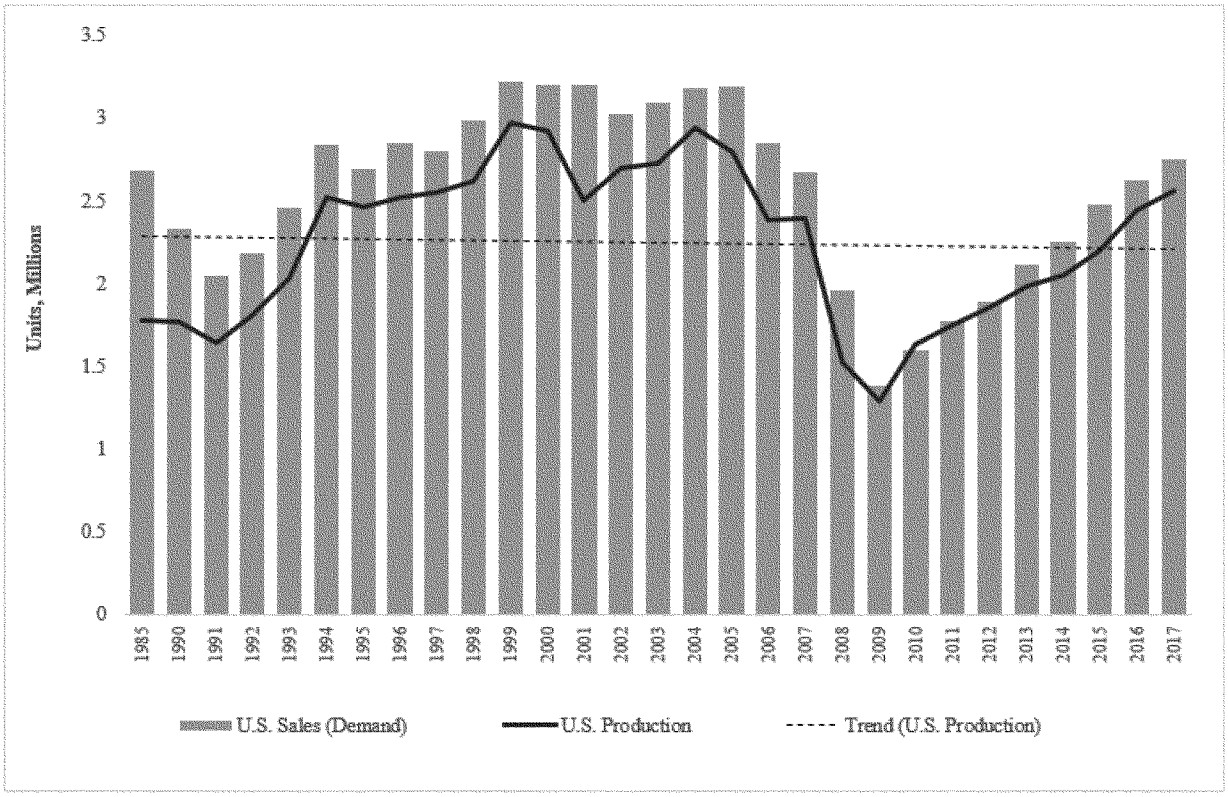
Source: Wards Intelligence InfoBank.

For light trucks, Figure 5 illustrates that U.S. demand held constant at 2.7 million light trucks in both 1985 and 2017, while U.S. production increased from 1.8 million light trucks to 2.6 million light trucks during the same period. Of this 2.6 million, approximately 2.0 million trucks were sold in the United States in 2017.[70] During the same period, imports of light trucks decreased by 24 percent, from 1.1 million to 833,000.[71]

[70] Wards Intelligence InfoBank and Department of Commerce, Census Bureau.

[71] Department of Commerce, Census Bureau. The United States has imposed a 25 percent tariff on imports of light trucks since 1964 pursuant to Presidential Proclamation 3564 in 1964. U.S. Presidential Proclamation No. 3564, *Proclamation Increasing Rates of Duty on Specified Articles,* December 4, 1963, 77 Stat. 1035–1036, *https://www.govinfo.gov/content/pkg/STATUTE-77/pdf/STATUTE-77-Pg1035.pdf.*

Figure 5: U.S. Light Truck Production Relative to Demand

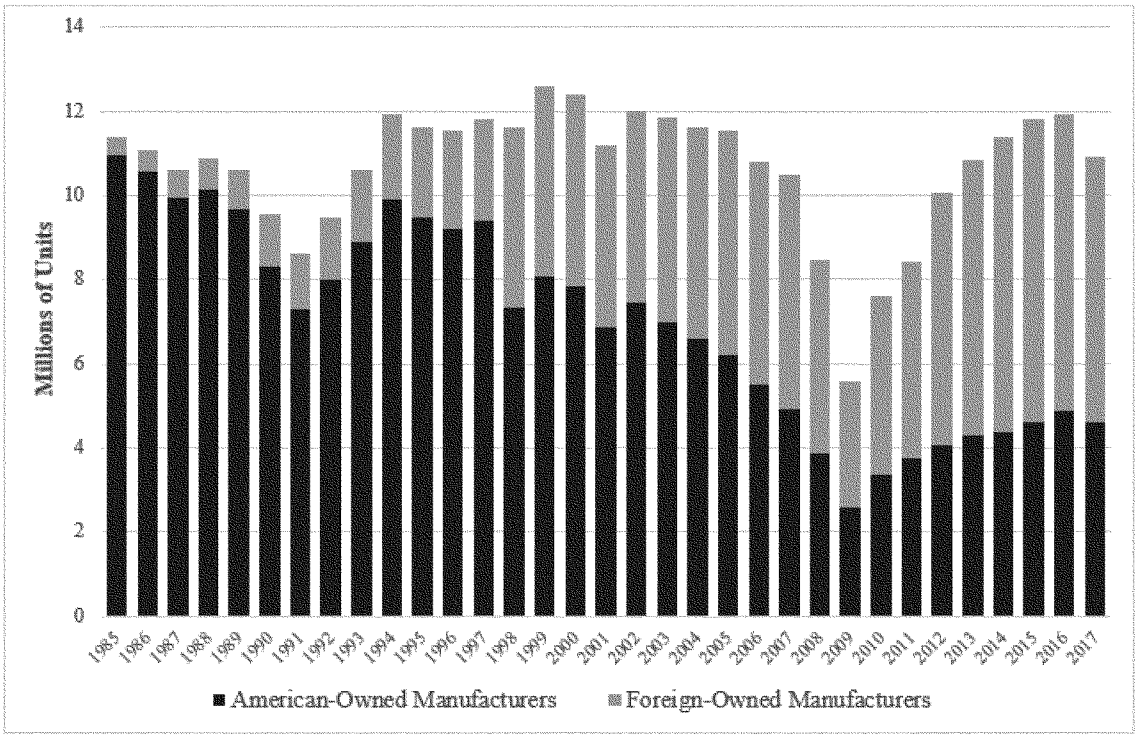


Source: Wards Intelligence InfoBank.

Notably, the domestic performance of American-owned automobile manufacturers (GM, Ford and Tesla) underpins the dramatic contraction of production volumes in the United States. As shown in Figure 6, in 1985, American-owned automobile facilities in the United States manufactured 11.0 million automobiles, representing 97 percent of overall domestic (American- and foreign-owned) production of automobiles. By 2017, American-owned production fell to 4.6 million automobiles, amounting to 42 percent of domestic automobile production (*i.e.,* a decline of 6.3 million units), and production by American-owned firms accounted for only 22 percent of total U.S. sales.[72]

[72] Figure 6 accounts for the fact that Chrysler became foreign-owned in 1998. *See supra* note 6.

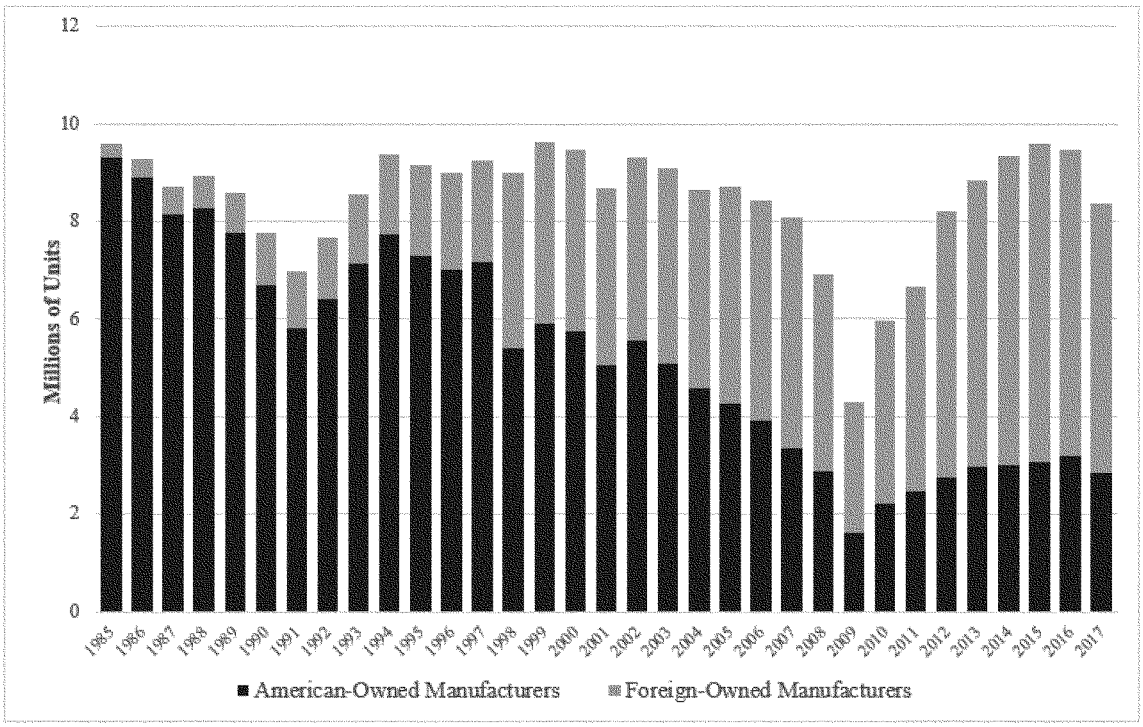
Figure 6: Automobile Production in the United States by American-Owned and Foreign-Owned Manufacturers



Source: Wards Intelligence InfoBank. (From 1998 forward Chrysler is foreign-owned.)

Figure 7 illustrates a similar trend for American-owned producers in the passenger vehicle segment over the course of the past 32 years. In 1985, American-owned U.S. manufacturers produced 9.3 million passenger vehicles (sedans, SUVs, CUVs, and vans), representing 97 percent of domestic (American- and foreign-owned) production. By 2017, American-owned production fell to 2.8 million passenger vehicles, representing just 34 percent of domestic production and 17 percent of domestic sales. As set forth in Section VI.C, this decline in production depicts the loss of American-owned producers' competitive position in the U.S. market (and globally, as described above), with the consequence that declining sales revenue has weakened the United States' ability to maintain a leadership position in R&D investments needed to develop technologies that are critical to national defense.

Figure 7: Passenger Vehicle Production in the United States by American-Owned and Foreign-Owned Manufacturers

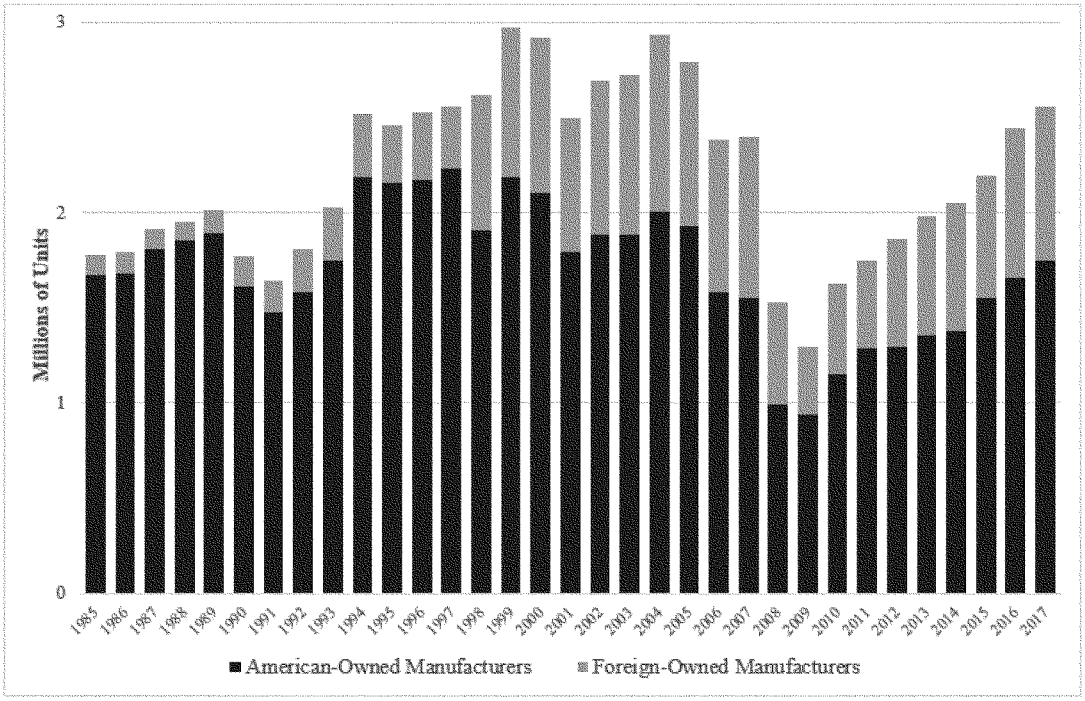


Source: Wards Intelligence InfoBank. (From 1998 forward Chrysler is foreign-owned.)

For light trucks, American-owned U.S. manufacturers have also experienced a declining share of U.S. production over the past three decades. They accounted for 94 percent of domestic production in 1985 (1.67 million units), a share that decreased to 68 percent (1.75 million units) in 2017.[73] This relatively narrower decline is attributed to U.S. consumers' preferences for American-made brands and models of light trucks, and the 25 percent tariff imposed by the United States on imports of light trucks since 1964.

[73] Wards Intelligence InfoBank.

Figure 8: Light Truck Production in the United States by American-Owned and Foreign-Owned Manufacturers



Source: Wards Intelligence InfoBank. (From 1998 forward Chrysler is foreign-owned.)

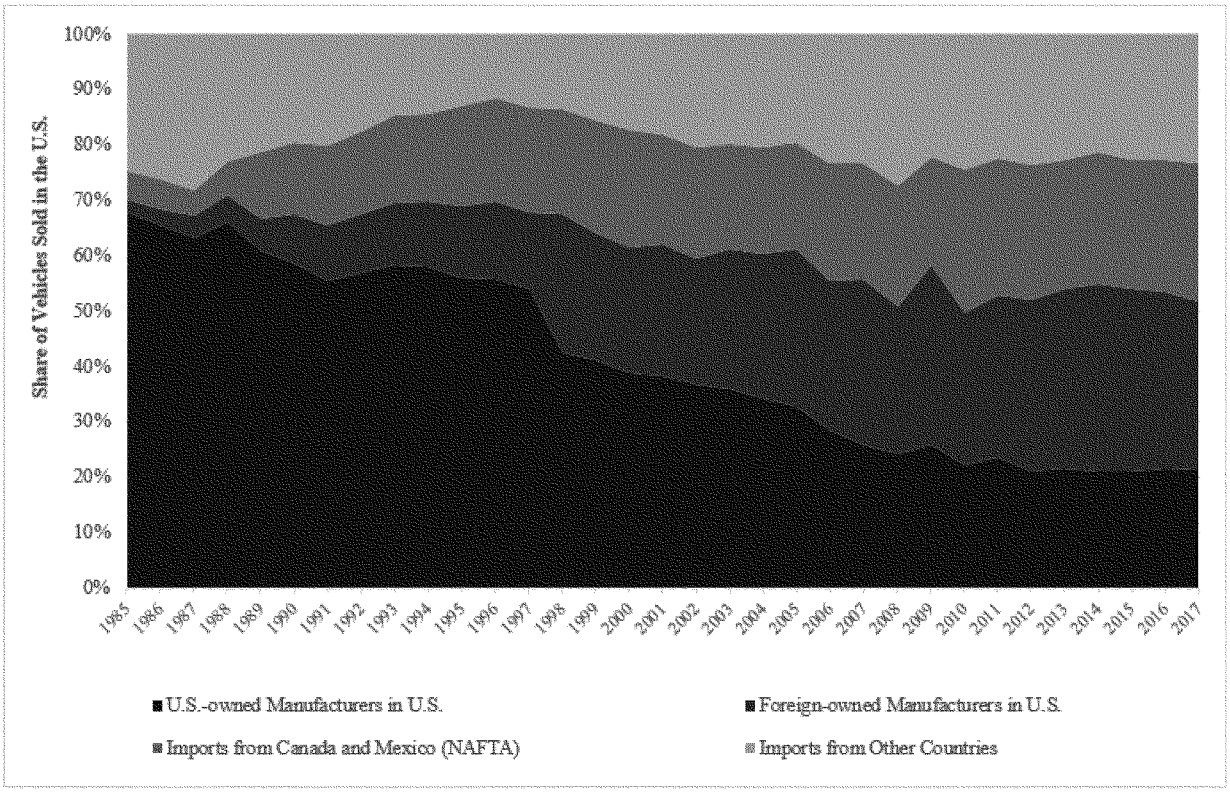
Even accounting for the strong presence of American-owned producers in the light truck segment, the overall competitive position of American-owned automobile producers has been weakening over time, as American-owned production volumes overall have steadily declined. Expressed as a percentage of overall U.S. demand for automobiles, the market share held by American-owned automobile manufacturers has contracted sharply from 67 percent in 1985 (10.5 million units produced and sold in the United States) to 22 percent in 2017 (3.7 million units produced and sold in the United States) as illustrated in Figure 9, with increases in demand and lost American-owned market share captured by both imports and foreign-owned manufacturers in the United States.[74] [TEXT REDACTED].[75] In other words, the share of the U.S. market captured by imports *plus* vehicles produced in the United States by foreign-owned firms increased from 33 percent in 1985 to 78 percent in 2017.[76]

[74] Wards Intelligence InfoBank; Department of Commerce, Census Bureau.

[75] U.S. Producers' Survey Responses, Question 2b. In 2017, American-owned firms produced and sold in the U.S. market [TEXT REDACTED].

[76] Wards Intelligence InfoBank; Department of Commerce, Census Bureau.

Figure 9: U.S. Production and Imports of Automobiles, Share of U.S. Sales

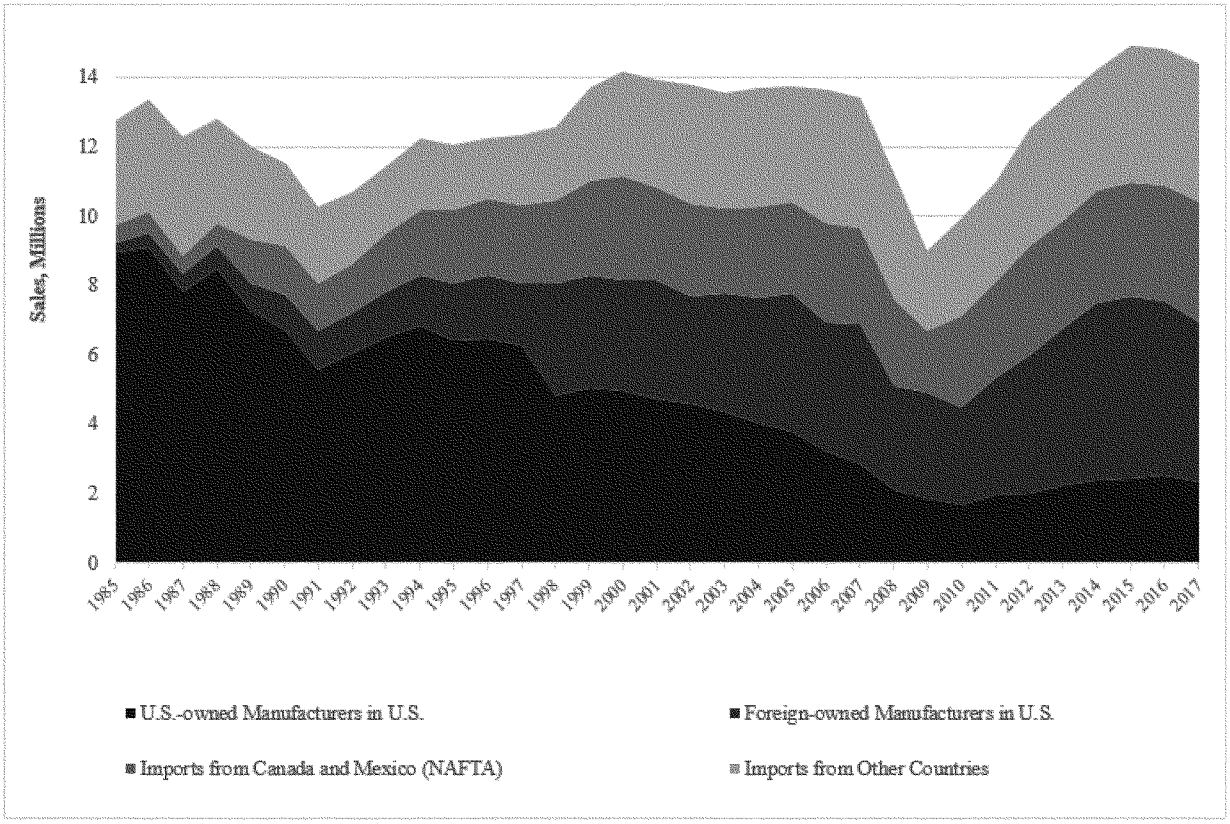


Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau. (From 1998 forward Chrysler is foreign-owned.)

For passenger vehicle sales where head-to-head competition with foreign producers is greatest, Figure 10 shows that from 1985 to 2017 the market share held by American-owned firms' domestic production declined from 70 percent to 16 percent.[77] Also significant is the fact that the market share claimed by light trucks produced in the United States by American-owned manufacturers declined by eight percent over the same period, as shown in Figure 11. American-owned manufacturers now hold less than half (*i.e.,* 47.7 percent) of the U.S. market for light trucks. Section VI.A.3 below explains that imports of both passenger vehicles and light trucks have displaced American-owned U.S. production and threaten the ability of American-owned producers to invest in the R&D that is critical to maintaining technological innovation that enables America to maintain global military superiority.

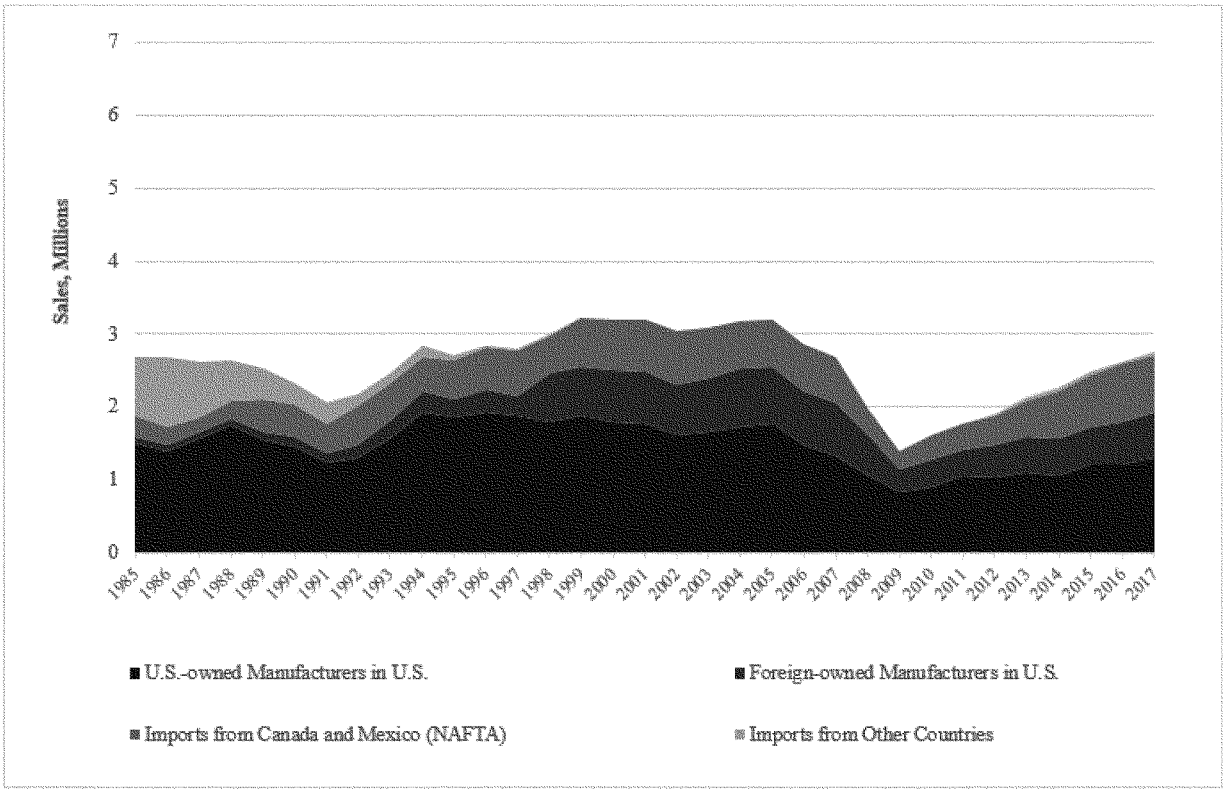
[77] Wards Intelligence InfoBank.

Figure 10: U.S. Production and Imports of Passenger Vehicles, Share of U.S. Sales



Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau. (From 1998 forward Chrysler is foreign-owned.)

Figure 11: U.S. Production and Imports of Light Trucks, Share of U.S. Sales



Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau. (From 1998 forward Chrysler is foreign-owned.)

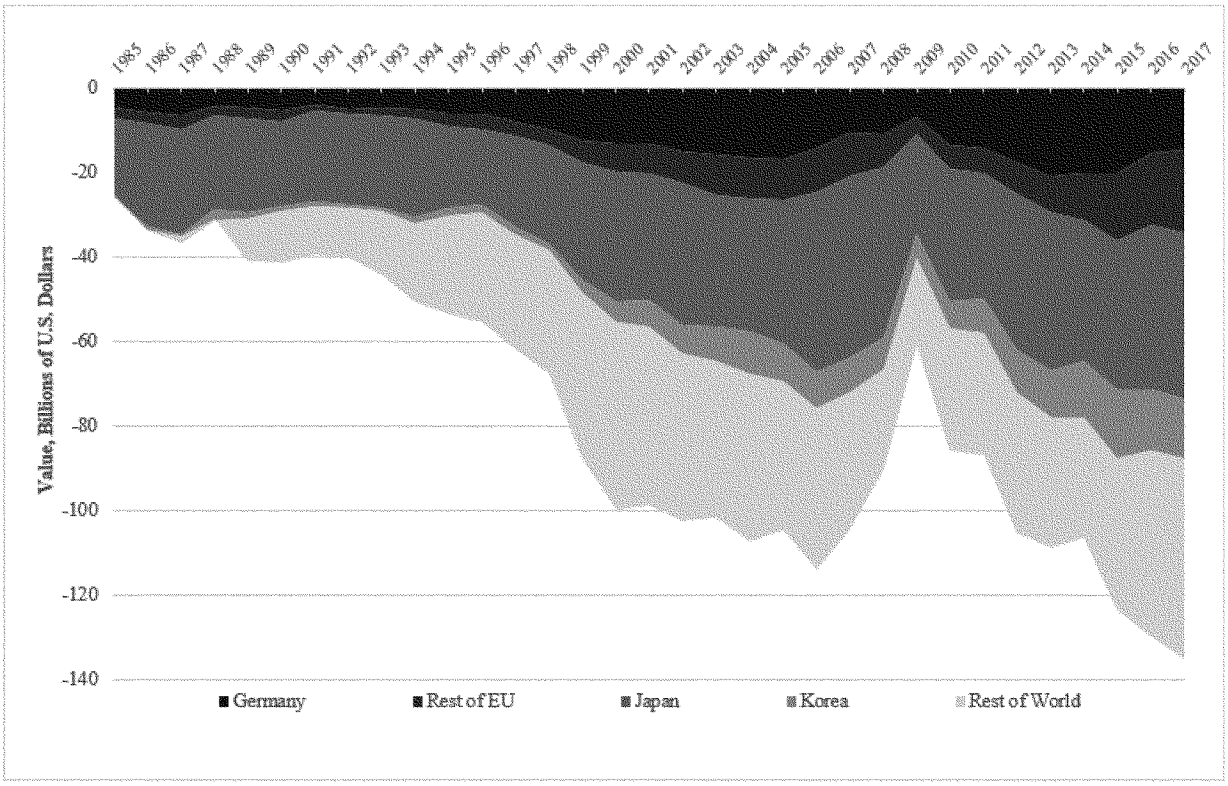
2. Market Penetration by Automobile Imports Is Significant

Automobile producers continuously strive to increase production scale to maximize profits. Indeed, scale is important because the enormous startup costs associated with the launch of a new production line must be amortized over substantial production and sales volumes in order to maximize revenue and minimize unit costs. As set forth in Appendix F, because automobile producers headquartered in the EU, Japan, South Korea, and China are protected from import competition in their respective home markets, these foreign producers are able to utilize significant sales profits in those home markets to heighten production to levels in excess of volumes needed to supply their respective domestic markets. Those firms consequently become increasingly export focused. Because the United States has the second largest automobile demand market in the world,[78] imposes a low 2.5 percent tariff on imports of passenger vehicles, and has a strong economy that allows manufacturers to maximize profits, foreign automobile producers take advantage of the open U.S. market to unload excess production at significant financial gain. Figure 12 illustrates this point using the United States' trade deficit in automobiles with Germany, Japan, and the rest of the world.[79]

[78] According to Wards Intelligence InfoBank, China is the largest consumer market for automobiles.

[79] This represents nominal figures, which do not take into account inflationary and foreign exchange changes over time.

Figure 12: U.S. Deficit in Automobiles with Trading Partners



Source: Department of Commerce, Census Bureau.

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This trade deficit underscores the significant disadvantage that U.S. automobile producers have internationally as a result of protected markets abroad. In 2017, manufacturers in the United States exported 2.0 million units ($56.9 billion U.S. dollars) compared to imports of automobiles from abroad of 8.3 million units ($191.7 billion U.S. dollars).[80]

From 1985 to 2017, overall imports of automobiles from all countries almost doubled from 4.6 million units to 8.3 million units, representing an increase from 30 percent of U.S. market share in 1985 to 48 percent in 2017 as shown in Figure 13.[81] As noted above, of the remaining 52 percent of U.S. market share, foreign-owned U.S. manufacturing operations account for 30 percent and American-owned U.S. manufacturing operations account for the remaining 22 percent. The fact that imports and foreign-owned production of automobiles in the United States accounted for 32 percent of the U.S. market share in 1985 but now hold 78 percent of the U.S. market, and the fact that American-owned automobile production in the United States declined by 6.3 million units over the same period (from 11.0 million units to 4.6 million units), underscores the displacement of American-owned production in the United States by imports and by foreign-owned manufacturers' U.S. production.[82]

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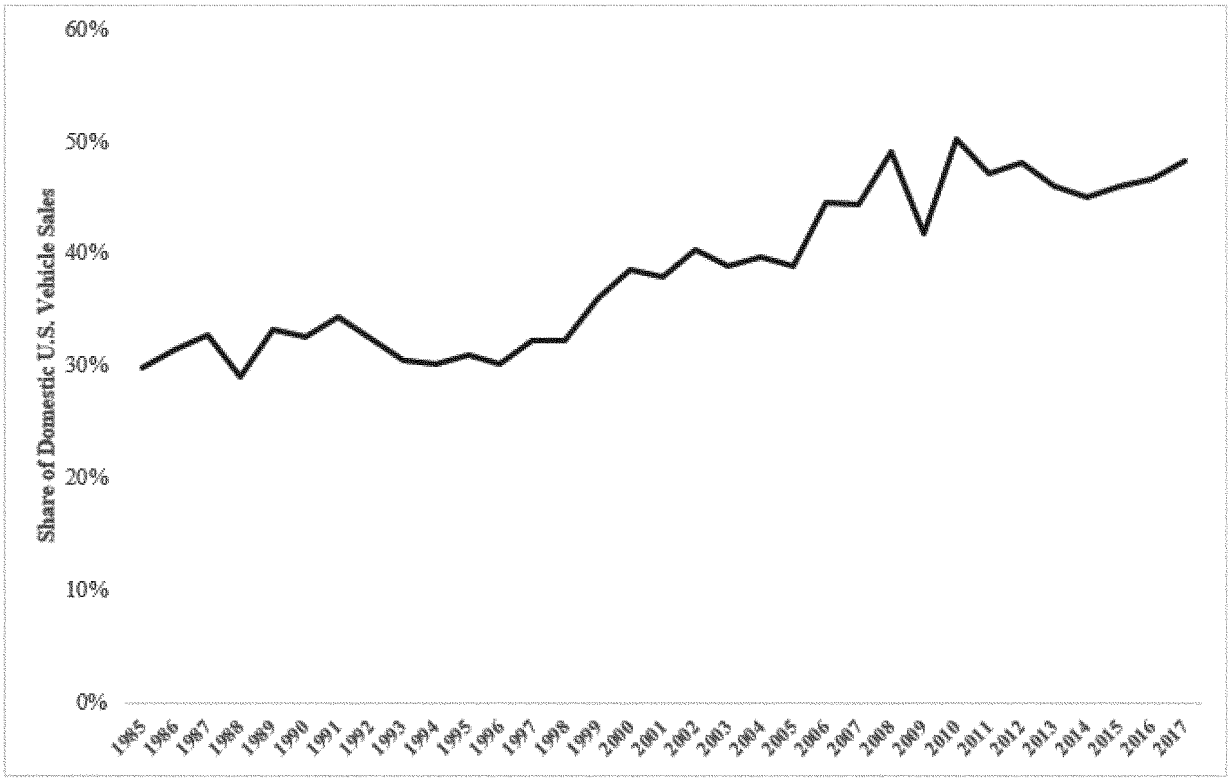
[80] Department of Commerce, Census Bureau.

[81] Wards Intelligence InfoBank; Department of Commerce, Census Bureau.

[82] *Id.*

Figure 13: Rise in Imports of Automobiles into the United States



Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau. Calculated by Department of Commerce.

By both volume and value, Mexico, Canada, Japan, South Korea and the EU account for nearly 98 percent of automobiles imported into the United States, although China is planning to rapidly grow exports to the United States as well.[83] Table 4 below lists the top sources of automobile imports into the United States.

Table 4: Top Sources of Automobile Imports into the United States in 2017

PARTNER	Import (Customs) Value, US$	Share of Total
WORLD	191,748,525,445	-
NAFTA	89,443,769,290	46.65%
EU	42,814,095,422	22.33%
Japan	39,781,128,900	20.75%
Korea	15,731,937,656	8.20%
China	1,455,678,215	0.76%
Rest of World	2,521,915,962	1.32%

PARTNER	Number of Vehicles	Share of Total
WORLD	8,271,840	-
NAFTA	4,271,298	51.64%
Japan	1,725,757	20.86%
EU	1,159,947	14.02%
Korea	929,419	11.24%
China	58,515	0.71%
Rest of World	126,904	1.53%

Source: Department of Commerce, Census Bureau.

U.S. imports of light trucks are subject to a 25 percent tariff rate, except where the tariff is removed by an FTA such as NAFTA.[84] Consequently, there is a notable lack of import competition from non-FTA regions but significant import

[83] China's intentions to dominate production of advanced technologies such as electric vehicles is detailed in the Section 301 Report on China prepared by the United States Trade Representative. A 2009 Chinese Central Government ''Opinion'' targets a 10 percent share of global automobile parts exports for Chinese automobile producers by 2020. Several provinces including Anhui, Chongqing, and Zhejiang have issued 5-year plans (their 13th) seeking increased automotive exports in response to these directives. *See Findings of the Investigation Into China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act of 1974,* Office of the United States Trade Representative, Executive Office of the President, March 22, 2018, *https://ustr.gov/sites/default/files/Section%20301%20FINAL.PDF* at 139. *See also* Shai Oster, *Excess auto capacity in China could leave dents in car makers,* Wall Street Journal, November 17, 2005, *https://www.wsj.com/articles/SB113218114486399413.*

[84] International Trade Commission, *Official Harmonized Tariff Schedule, https://www.usitc.gov/tata/hts/index.htm.*

penetration from Mexico where light trucks are largely produced for the U.S. market. In 2017, imports from Mexico represented over 96 percent of the overall volume and value of light truck imports into the United States.

Table 5: Top Sources of Light Truck Imports into the United States in 2017

PARTNER	Import (Customs) Value, US$	Share of Total
WORLD	18,346,921,785	-
NAFTA	17,903,922,414	97.59%
EU	423,727,370	2.31%
Japan	13,294,493	0.07%
Australia	2,482,036	0.01%
China	1,431,528	0.01%
Rest of World	2,063,944	0.01%

PARTNER	Number of Vehicles	Share of Total
WORLD	832,755	-
NAFTA	801,486	96.25%
EU	30,029	3.61%
Japan	771	0.09%
China	174	0.02%
Australia	141	0.02%
Rest of World	154	0.02%

Source: Department of Commerce, Census Bureau.

In contrast, because U.S. imports of passenger vehicles are subject to a low 2.5 percent tariff, or zero tariff from FTA countries,[85] there is significant import penetration in this segment. By both volume and value, Mexico, Canada, Japan, South Korea and the EU account for over 97 percent of the overall U.S. import volume of passenger vehicles.

Table 6: Top Sources of Passenger Vehicle Imports into the United States in 2017

PARTNER	Import (Customs) Value, US$	Share of Total
WORLD	173,401,603,660	-
NAFTA	71,539,846,876	41.26%
EU	42,390,368,052	24.45%
Japan	39,767,834,407	22.93%
Korea	15,731,917,446	9.07%
China	1,454,246,687	0.84%
Rest of World	2,517,390,192	1.45%

PARTNER	Number of Vehicles	Share of Total
WORLD	7,439,085	-
NAFTA	3,469,812	46.64%
Japan	1,724,986	23.19%
EU	1,129,918	15.19%
Korea	929,418	12.49%
China	58,341	0.78%
Rest of World	126,610	1.70%

Source: Department of Commerce, Census Bureau.

For every automobile market segment, moreover, the U.S. market has witnessed an acceleration in imports over the past five years. [TEXT REDACTED].[86] In 2017, imports of automobiles by foreign-owned manufacturers in the United States accounted for [TEXT REDACTED] of total import volume, whereas imports by American-owned manufacturers accounted for [TEXT REDACTED] of the import volume.[87]

Table 7: Volume of U.S. Imports of Automobiles by Vehicle Segment

Imports from Top 10 Sources by Type (Units)					
Item	2013	2014	2015	2016	2017
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]
[TEXT REDACTED					]

Source: U.S. Producers' Survey Responses, Question 4b.
([TEXT REDACTED]).

[85] *Id.*

[86] U.S. Producers' Survey Responses, Question 4b.

[87] *Id.*

Table 8A further shows that, by market segment, imports were largely sourced from producers in [TEXT REDACTED]. [TEXT REDACTED]. Whereas American-owned producers' imports in 2017 from North America totaled [TEXT REDACTED] of their overall imports, foreign-owned automobile producers' imports from regions outside North America accounted for [TEXT REDACTED] of their overall imports. In other words, while American-owned automobile producers expanded operations to [TEXT REDACTED] to remain competitive in the U.S. market, foreign-owned producers not only took advantage of the [TEXT REDACTED] integrated North American supply chain to reap competitive gains in the U.S. market, [TEXT REDACTED] to displace U.S. production by American-owned firms. In fact, [TEXT REDACTED] of foreign-owned producers' [TEXT REDACTED]. More specifically, EU automobile producers in the United States [TEXT REDACTED] of their automobile [TEXT REDACTED], Japanese producers in the United States [TEXT REDACTED] of their automobile [TEXT REDACTED], and South Korean producers in the United States [TEXT REDACTED] of their automobile [TEXT REDACTED].[88]

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Table 8A: Sources of U.S. Imports of Automobiles for All Market Segments

2017 Imports by Source and Type (Units), Top 10 by Total			
Country	Sedans/SUVs/CUVs	Light Trucks	Vans
[TEXT REDACTED			
			]

Source: U.S. Producers' Survey Responses, Question 4b.

Table 8B: Sources of American-Owned U.S. Manufacturers' Imports of Automobiles for All Market Segments

2017 Imports by Source and Type (Units), Top 10 by Total			
Country	Sedans/SUVs/CUVs	Light Trucks	Vans
[TEXT REDACTED			
			]

Source: U.S. Producers' Survey Responses, Question 4b.

[88] *Id.*

Table 8C: Sources of Foreign-Owned U.S. Manufacturers' Imports of Automobiles for All Market Segments

2017 Imports by Source and Type (Units), Top 10 by Total			
Country	Sedans/SUVs/CUVs	Light Trucks	Vans
[TEXT REDACTED			
			]

Source: U.S. Producers' Survey Responses, Question 4b.

Significantly, imports now exceed American-owned production in the United States. As Table 9 demonstrates, in 2017 the United States imported passenger vehicles and light trucks equal to 263 percent of American-owned passenger vehicle production and 48 percent of domestic light truck production, respectively. American-owned producers were not operating at full capacity in 2017 and, thus, had the ability to produce more vehicles.[89]

Table 9: American-Owned Production in the United States Compared to Imports

Vehicle Type	Production Volume in 2013 (units)	Production Volume in 2017 (units)	Import Volume in 2013 (units)	Import Volume in 2017 (units)
Passenger Vehicles	2,952,994	2,832,439	6,633,574	7,439,085
Light Trucks	1,351,645	1,750,198	517,241	832,755
Total	4,304,639	4,582,637	7,150,815	8,271,840

Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau.

3. Low Priced Foreign-Owned Automobile Production and Imports Have Caused Significant Market Penetration in the United States and Have Suppressed U.S. Producers' Prices

Imported and domestically-produced automobiles compete head-to-head in the same geographic markets based primarily on price, brand, and quality, with price being a significant factor driving consumers' purchasing decisions.[90] From 2005 to 2017, the average unit value (''AUV'') on retail sales of automobiles in the United States increased by 13.0 percent,[91] which is well below the 28.3 percent increase in consumer prices over this period. [92] Further, for both passenger vehicles and light trucks each year during the 2013 to 2017 period, Tables 10A, 10B, and 10C show that [TEXT REDACTED] and hence contributed to the suppression of automobile prices in the United States market.

[89] Board of Governors of the Federal Reserve System (US), *G.17. Capacity Utilization: Durable Manufacturing: Automobiles and parts, https://www.federalreserve.gov/releases/g17/current/.*

[90] Christian Wardlaw, *10 Top Reasons Why People Buy Specific Cars,* New York Daily News, Mar. 4, 2016, *https://www.nydailynews.com/autos/buyers-guide/10-top-reasons-people-buy-specific-cars-article-1.2552707.*

[91] Wards Intelligence InfoBank.

[92] Department of Labor, Bureau of Labor Statistics, Consumer Price Index, *https://www.bls.gov/cpi/* (accessed January 24, 2019).

Table 10A: Average Unit Value of Automobiles Produced in the U.S.

	2013	2014	2015	2016	2017
Passenger Vehicles	[TEXT	REDACTED			]
Light Trucks	[TEXT	REDACTED			]
Overall Average for All Automobiles	[TEXT	REDACTED			]

Source: U.S. Producers' Survey Responses, Question 2b.

Table 10B: Average Unit Value of Automobiles Produced in the U.S., American-Owned Manufacturers

	2013	2014	2015	2016	2017
Passenger Vehicles	[TEXT	REDACTED			]
Light Trucks	[TEXT	REDACTED			]
Overall Average for All Automobiles	[TEXT	REDACTED			]

Source: U.S. Producers' Survey Responses, Question 2b.

Table 10C: Average Unit Value of Automobiles Produced in the U.S., Foreign-Owned Manufacturers

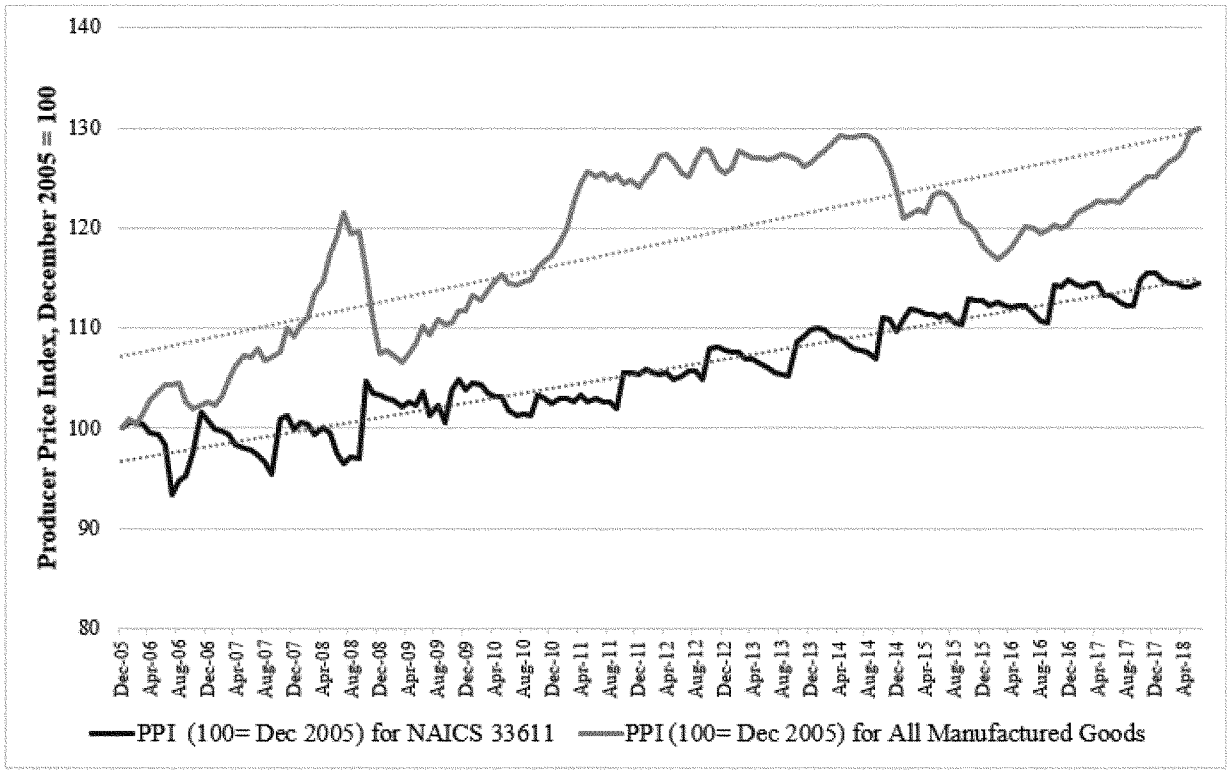
	2013	2014	2015	2016	2017
Passenger Vehicles	[TEXT	REDACTED			]
Light Trucks	[TEXT	REDACTED			]
Overall Average for All Automobiles	[TEXT	REDACTED			]

Source: U.S. Producers' Survey Responses, Question 2b.

Figure 14 moreover shows that, between 2005 and 2017, the producer price index for automobiles increased by 15 percent while the producer price index for all manufactured goods increased by 27 percent.[93]

[93] Department of Labor, Bureau of Labor Statistics, Producer Price Index (PPI) for Automobiles.

Figure 14: Increase of U.S. Producer Price Index for Automobiles Compared to All Manufactured Goods



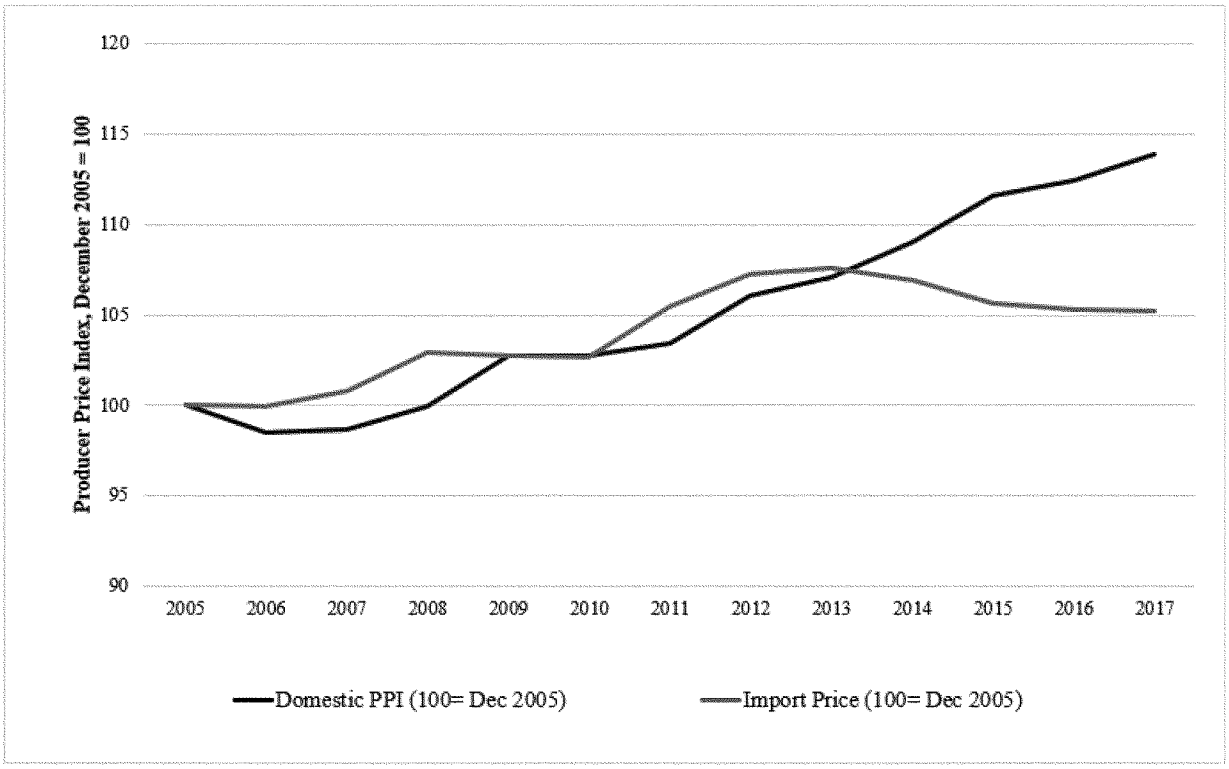
Source: Bureau of Labor Statistics, PPI Database, adjusted by U.S. Department of Commerce.

(Data adjusted to rebase the index period to December 2005.)

The slow growth of U.S. prices for automobiles is also attributable to the low prices of foreign imports. As shown in Figure 15, since 2005, the average price of a domestically produced automobile in the United States increased by 14 percent compared to a 5 percent increase in the average price of imported automobiles.[94] These data demonstrate that low vehicle import prices permitted imports to capture significant market share from U.S. producers.

[94] *Id.*

Figure 15: Increase of U.S. Producer Price of Automobiles Compared to the Price of Imported Automobiles (NAICS 33611)



Source: Bureau of Labor Statistics, PPI Database, adjusted by Department of Commerce. (Data adjusted to rebase the index period to December 2005.)

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When this analysis is disaggregated by passenger vehicles and light trucks for a more recent comparison period, [TEXT REDACTED], as shown in Figures 16 and 17 below. With respect to passenger vehicles, [TEXT REDACTED]. For light trucks, [TEXT REDACTED].[95]

Figure 16: AUVs of Passenger Vehicles: Domestic Production vs. Imports

[TEXT REDACTED]

Figure 17: AUVs of Light Trucks: Domestic Production vs. Imports

[TEXT REDACTED]

A more detailed examination of import prices reveals that differences in prices have been most significant with respect to imports from [TEXT REDACTED]. [TEXT REDACTED].[96]

Figure 18: AUVs of Passenger Vehicles: Domestic Production vs. Imports

[TEXT REDACTED]

Figure 19: AUVs of Light Trucks: Domestic Production vs. Imports

[TEXT REDACTED]

Low-priced imports have placed significant competitive pressure on U.S. producers throughout the market by preventing the price increases that would otherwise have occurred. As explained below, from 2013 to 2017, [TEXT REDACTED], while during this period, the industry's total cost of goods sold (''COGS'') [TEXT REDACTED] (from [TEXT REDACTED].[97] Accordingly, the [TEXT REDACTED].[98]

In short, imported automobiles have prevented American-owned automobile producers from increasing sales prices [TEXT REDACTED] in producers' costs for producing vehicles in the United States. As explained in Section VI.B and VI.C, this has negatively impacted American-owned producers' ability to invest in technological advancements that are critical to U.S. national security needs.

B. Imports of Automobile Parts in Such Quantities as Are Presently Found Threaten the Viability of the U.S. Automobile Parts Industry

The automobile parts industry is experiencing a significant revolution in technological advancements. In the area of intelligent mobility technology, over the past decade, the electrical components industry has made significant strides in advanced sensor systems, vehicle automation, and vehicle connectivity. All major international automobile producers are heavily investing in technology, and advancements in electronic components are expected to accelerate over the course of the next decade as automobiles transition to full automation capabilities. In the area of light duty vehicle propulsion, automobile engine and transmission technologies have rapidly progressed because manufacturers, in response to

[95] U.S. Producers' Survey Responses, Questions 2b; Department of Commerce, Census Bureau.

[96] U.S. Producers' Survey Responses, Question 2b; *see also* Mike Monticello, *Are Pickup Trucks Becoming the New Family Cars?,* Consumer Reports, Feb. 22, 2013, *https://www.consumerreports.org/pickup-trucks/are-pickup-trucks-becoming-the-new-family-car/.*

[97] U.S. Producers' Survey Responses, Questions 2b and 3.

[98] U.S. Producers' Survey Responses, Question 3.

increasingly stringent emission and fuel economy regulations, have invested in a broad portfolio of different lightweighting propulsion technologies, including internal combustion engines, plug-in hybrid vehicles, and fuel cell technologies. As set forth in Section VI.C., these innovations are integral to advancements in military vehicle capabilities and, hence, U.S. defense requirements.

1. Imports of Automobile Parts Have Displaced U.S. Production, and the United States Has Become Dependent on Imported Automobile Parts That Are Critical to Defense Applications and National Security

In consultation with the DOD, the Secretary has specifically determined that automobile engines and parts, transmissions and powertrain parts, and electrical components are essential to national security, and [TEXT REDACTED].[99] [TEXT REDACTED].[100] Further, U.S. automobile producers are now more than ever relying on imports of such automobile parts to satisfy their production needs.

In fact, every U.S. producer of passenger vehicles—whether American-owned or foreign-owned—imports a significant volume of automobile parts for its vehicle production operations in the United States. [TEXT REDACTED].[101] As shown in Table 11A, American-owned automobile producers have, on average, [TEXT REDACTED] [102] Further, both American-owned and foreign-owned producers reported [TEXT REDACTED] [TEXT REDACTED].[103] Table 11B below lists the major countries from which U.S. automobile producers (whether American- or foreign-owned) sourced automobile parts in 2017.

Table 11A: 2017 U.S. Domestic Content by Vehicle Type, American-Owned vs. Foreign-Owned Manufacturers

	American-Owned Manufacturers	Foreign-Owned Manufacturers
Sedans/SUVs/CUVs	[TEXT REDACTED	]
Light Trucks	[TEXT REDACTED	]
Vans	[TEXT REDACTED	]

Source: U.S. Producers' Survey Responses, Question 2b.

Table 11B: Top Sources of Imports for Specific Automobile Parts, American-Owned vs. Foreign-Owned Manufacturers

Automobile Part	Import Source, American-Owned Manufacturers	Import Source, Foreign-Owned Manufacturers
[TEXT REDACTED		]
[TEXT REDACTED		]
[TEXT REDACTED		]
[TEXT REDACTED		]

Source: U.S. Producers' Survey Responses, Questions 5a and 5c.

Substantial evidence demonstrates the extent to which import penetration has significantly weakened U.S. production. With respect to automobile engines, the United States has been a significant importer of completed engines since 1989 when it imported 3.0 million engines, or 29 percent of U.S. demand, for domestic automobile production.[104] Between 1989 and 2017, production of automobiles in the United States increased by 3 percent (from 10.6 million units to 10.9 million units), while imports of automobile engines increased by 32 percent (from 3.0 million units to 4.0 million units).[105] The 4.0 million units imported in 2017 represents 37 percent of U.S. demand. Over this period, imports of automobile engines from Mexico expanded by 1.1 million units (to 1.8 million units in 2017) and imports from Germany grew by 190,000 units (to 450,000 units in 2017).[106] By engine type, American-owned producers sourced [TEXT REDACTED] of engines domestically in the United States and foreign-owned producers sourced [TEXT REDACTED] of engines in the United States in 2015.[107]

Furthermore, U.S. automobile producers have become increasingly reliant on foreign suppliers for engine parts. In particular, from 1989 to 1999, the United States imported an average of $346 in parts per engine produced, which grew from 2010 to 2017 to an import average of $1,178 in parts per engine produced.[108] As illustrated by

[99] U.S. Producers' Survey Responses, Questions 10a and 10b.

[100] U.S. Producers' Survey Responses, Question 10b.

[101] U.S. Producers' Survey Responses, Question 2b. [Although average imported content was 35 percent, individual producers reported imported content shares as high as 70 percent for some market segments].

[102] *Id.*

[103] *Id.*

[104] Department of Commerce, Census Bureau; Wards Intelligence InfoBank. (Data prior to 1989 would not be directly comparable with data for 1989 forward due to classification changes.

[105] Department of Commerce, Census Bureau; Wards Intelligence InfoBank.

[106] Department of Commerce, Census Bureau.

[107] U.S. Producers' Survey Responses, Question 6. (2015 is the most recent year for which data were available.)

[108] Department of Commerce, Census Bureau; Wards Intelligence InfoBank. (This represents nominal figures, which do not take into account inflationary and foreign exchange changes over time. Appropriate ''real'' figures are not publicly available.)

Figure 20, U.S. engine manufacturers have, in large part, transitioned to assembly operations and away from manufacturing and innovation.[109]

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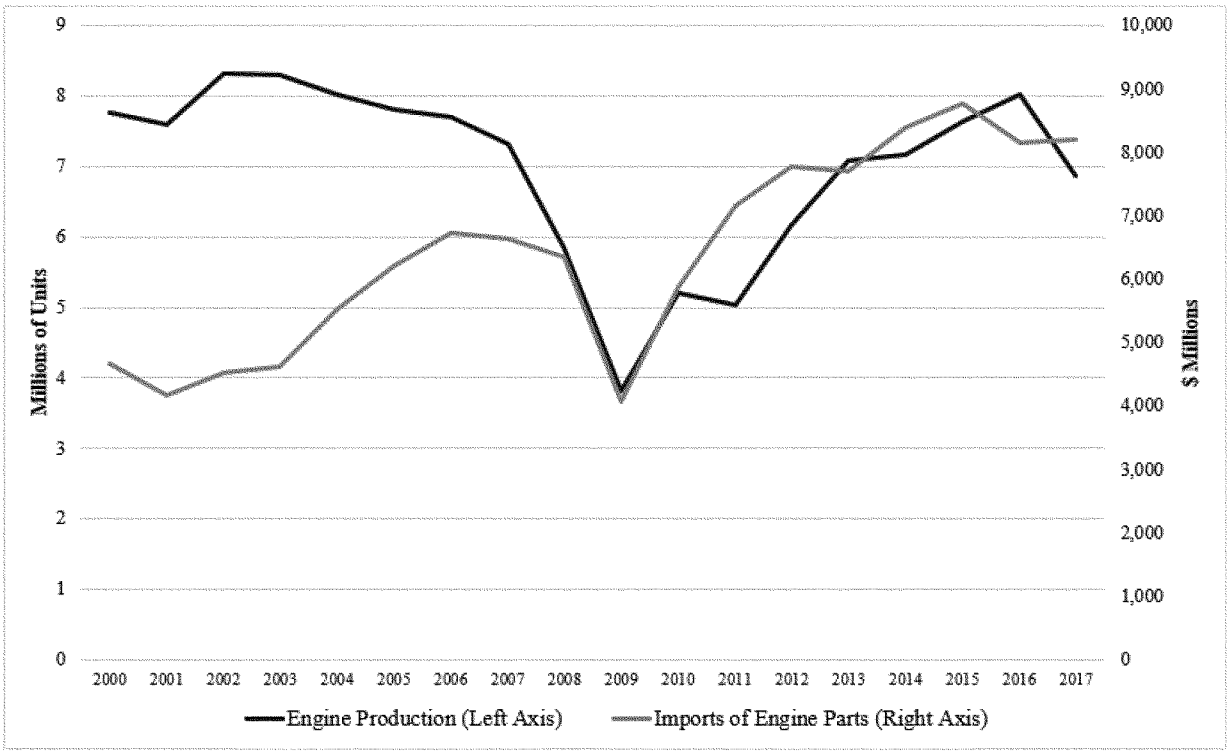
Figure 20: U.S. Engine Production for Domestic Use vs. Imports of Engine Parts



Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau. ('Domestic use' refers to use in automobiles produced and sold in the United States.)

With respect to automobile transmissions, the United States has long been a significant importer of completed transmissions. From 1989 to 2017, the United States imported, on average, 50 percent of transmissions used in domestic automobile manufacturing.[110] In 2017, automobile manufacturers in the United States imported 5.1 million completed transmissions representing 47 percent of domestic demand while domestic production captured the remaining 53 percent.[111] As with engines, American-owned producers sourced [TEXT REDACTED] of transmissions domestically in the United States whereas foreign-owned producers sourced [TEXT REDACTED] of their transmissions in the United States in 2015.[112]

In addition to import penetration by transmissions displacing domestic production, transmission producers in the United States have increasingly shifted to foreign suppliers for the parts needed to build transmissions. As shown in Figure 21, in 2000 the United States imported $457 in parts per transmission produced domestically. By 2017 imports had increased to $1,226 in parts per transmission produced domestically.[113] U.S. transmission producers are increasingly becoming assemblers; they are not developing emerging technologies associated with next-generation transmissions, and thereby are reducing the availability of the skills, equipment, and R&D needed to maintain global leadership in this important component of automotive production and defense mobility.

[109] *Id.* Although the value and complexity of automobile engines has increased over this period, the relative rate of growth of the average unit value of imported engines (up 179 percent from 1989 to 2017) and imported parts per domestically-produced engine (370 percent from 1989 to 2017) indicates that there is an increased reliance on imported parts by U.S. engine manufacturers.

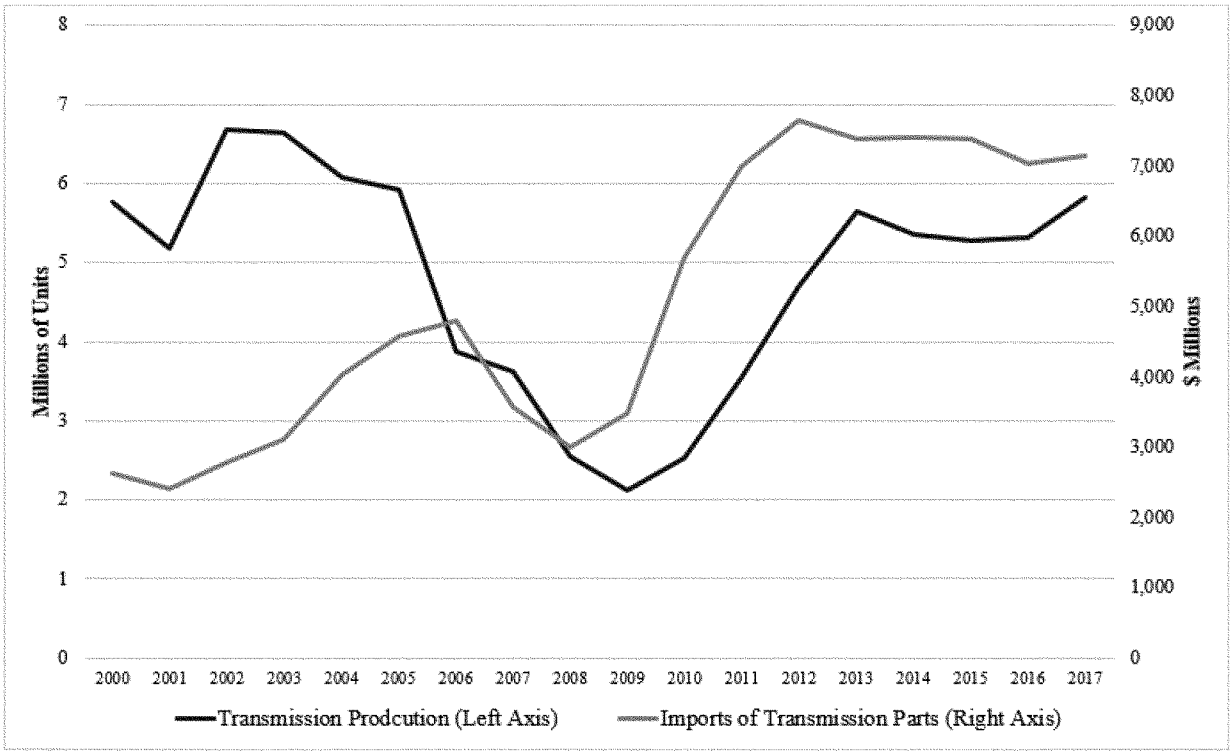
[110] Department of Commerce, Census Bureau; Wards Intelligence InfoBank. Department of Commerce calculations.

[111] *Id.*

[112] U.S. Producers' Survey Responses, Question 6. (2015 is the most recent year for which data were available.)

[113] Department of Commerce, Census Bureau; Wards Intelligence InfoBank. This represents nominal figures, which do not take into account inflationary and foreign exchange changes over time. Appropriate ''real'' figures are not publicly available. Includes HS–10 codes 8708996700, 8708996790, and 8708996890 in addition to the transmission parts listed in Section VIII to create a more consistent time series.

Figure 21: U.S. Transmission Production for Domestic Use vs. Imports of Transmission Parts



Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau. ('Domestic use' refers to use in vehicles produced and sold in the United States.) (Includes HS-10 codes 8708996700, 8708996790, and 8708996890 in addition to the transmission parts listed in Section VIII to create a more consistent time series.)

Finally, with respect to U.S. producers of electrical components, domestic production has also been displaced by imports, as shown in Figure 22. From 1999 to 2016 (latest available data), U.S. production of electrical components declined by 4 percent while U.S. demand grew steadily, with the result that imports captured all of the growth in overall U.S. demand.[114] In 1999, imports of electrical components represented 29 percent of U.S. demand by value, [115] and by 2016, imports grew to 56 percent of U.S. demand by value. [116] Further, American-owned producers sourced [TEXT REDACTED] of electrical components in the United States and foreign-owned producers sourced [TEXT REDACTED] of electrical components in the United States in 2015 (latest available data).[117]

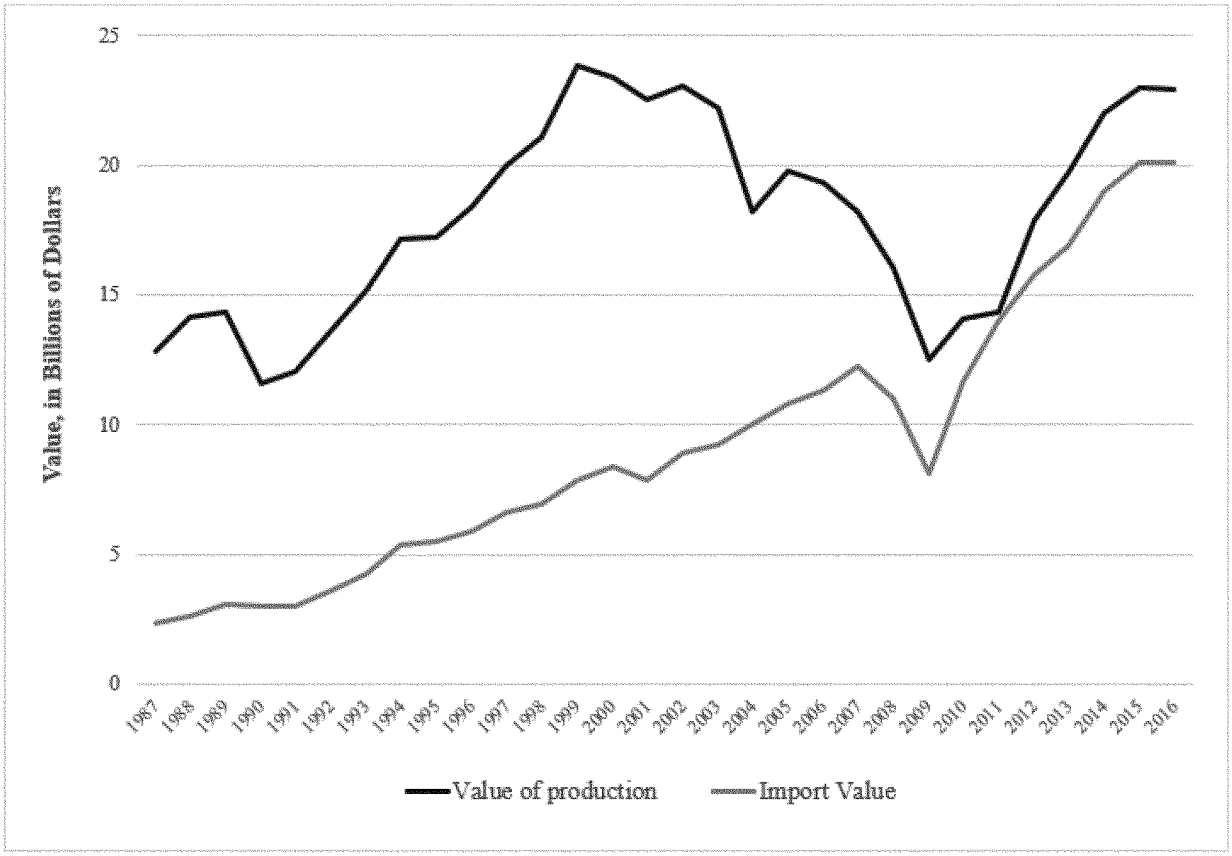
[114] Bureau of Labor Statistics, Industry Productivity & Costs Database, *https://www.bls.gov/lpc/;* Department of Commerce, Census Bureau.

[115] Demand is approximated to be U.S. production plus net imports (imports less exports).

[116] This refers to nominal value figures. However, over the same period, an output index estimating the change in real production shows a similar trend; U.S. output in the automobile electrical and electronic equipment sector in 2016 was 5 percent lower than output in 1999. Source: Bureau of Labor Statistics, Industry Productivity & Costs Database, *https://www.bls.gov/lpc/.*

[117] U.S. Producers' Survey Responses, Question 6.

Figure 22: Growth of Imports and U.S. Production of Automobile Electrical and Electronic Equipment



Source: Bureau of Labor Statistics, Industry Productivity & Costs Database and Department of Commerce, Census Bureau. (Automobile Electrical and Electronic Equipment defined as NAICS 33632.)

Tables 12A and 12B below illustrate the sourcing patterns of American-owned and foreign-owned automobile producers in the United States, [TEXT REDACTED].[118] Excessive imports have weakened the U.S. automobile parts manufacturing base, as these imported parts could have been produced domestically.

[118] U.S. Producers' Survey Responses, Question 6.

Table 12A: Domestic & Foreign Sourcing of Automobile Parts for U.S. Production, 2015

Component Type	Estimated Share of Components Manufactured In: United States	Other Countries
Engines - 4 Cylinder	[TEXT	REDACTED]
Engines - 6 Cylinder	[TEXT	REDACTED]
Engines - 8 or More Cylinder	[TEXT	REDACTED]
Transmissions - 7 or Fewer Gears	[TEXT	REDACTED]
Transmissions - 8 or More Gears	[TEXT	REDACTED]
Electronics and Controls	[TEXT	REDACTED]
Electrical Systems	[TEXT	REDACTED]

Source: U.S. Producers' Survey Responses, Question 6.

Table 12B: Domestic & Foreign Sourcing of Automobile Parts for U.S. Production, 2015, American-Owned vs. Foreign-Owned Manufacturers

	American-Owned Manufacturers		Foreign-Owned Manufacturers	
	Estimated Share of Components Manufactured In:		Estimated Share of Components Manufactured In:	
Component Type	United States	Other Countries	United States	Other Countries
Engines - 4 Cylinder	[TEXT	REDACTED		]
Engines - 6 Cylinder	[TEXT	REDACTED		]
Engines - 8 or More Cylinder	[TEXT	REDACTED		]
Transmissions - 7 or Fewer Gears	[TEXT	REDACTED		]
Transmissions - 8 or More Gears	[TEXT	REDACTED		]
Electronics and Controls	[TEXT	REDACTED		]
Electrical Systems	[TEXT	REDACTED		]

Source: U.S. Producers' Survey Responses, Question 6.

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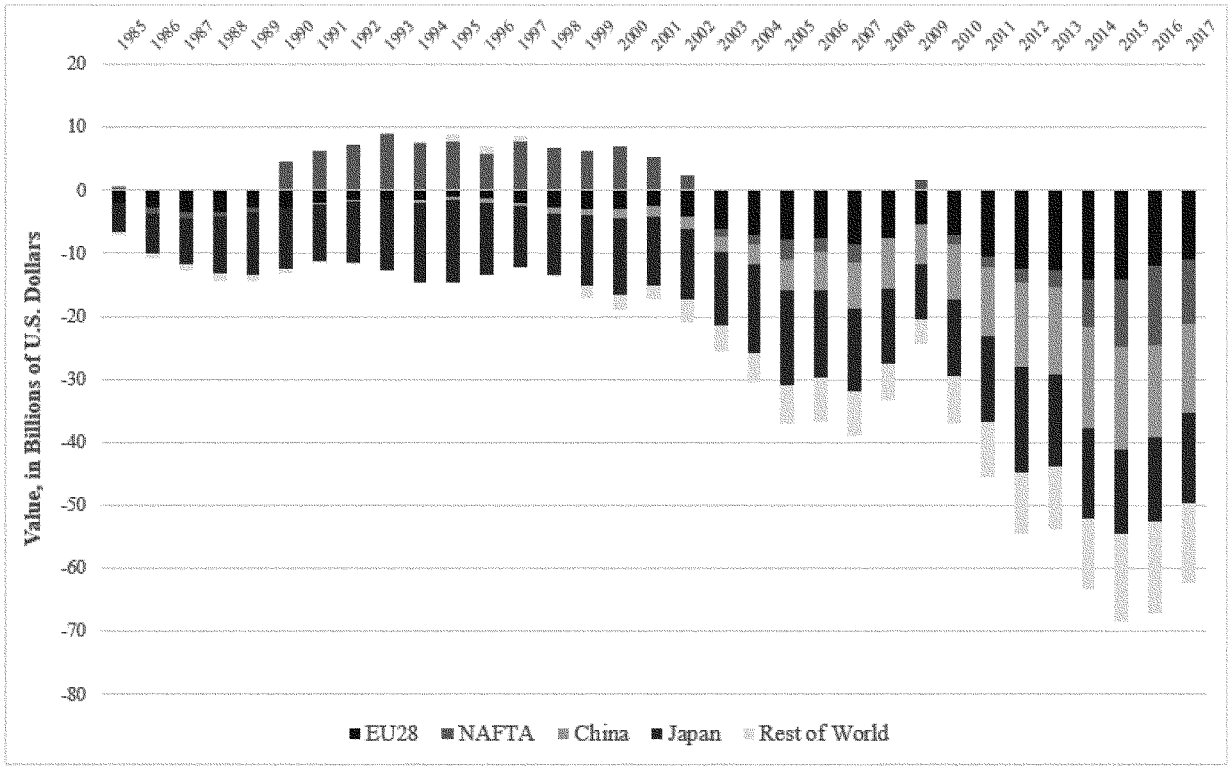
U.S. trade deficit data in Figures 23 and 24 further illustrate the dramatic extent to which domestic production of automobiles has become dependent on foreign-sourced parts. Although the United States has consistently incurred a trade deficit in automobile parts over the past 30 years, this deficit has increased to record levels within the past three years, reaching over $60 billion in 2017.[119]

[119] Department of Commerce, Census Bureau. This represents nominal figures, which do not take into account inflationary and foreign exchange changes over time. Appropriate ''real'' figures are not publicly available.

Figure 23: U.S. Trade Deficit in Overall Automobile Parts

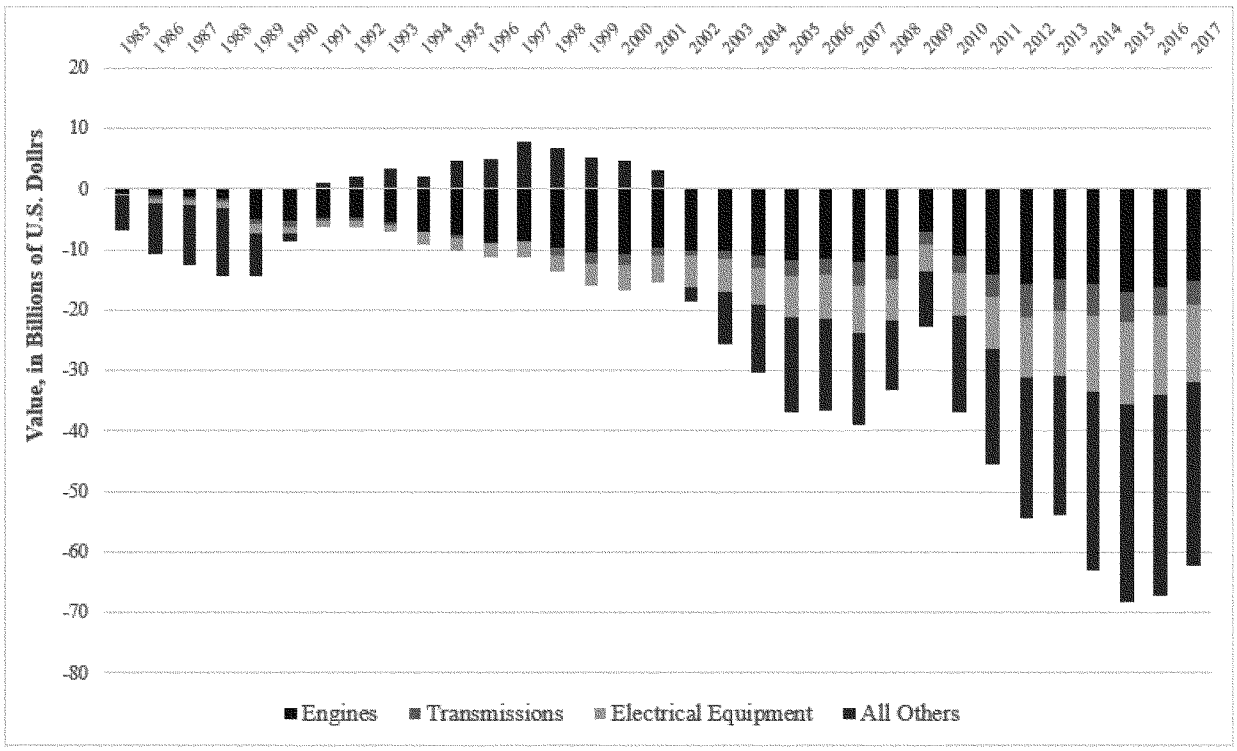


Source: Department of Commerce, Census Bureau.

Disaggregated by component type, the trade deficit in automobile engines and parts, transmissions and powertrain parts, and electrical components is equally as significant. Figure 24 shows that the trade deficit in engines and engine parts grew from a deficit of $0.7 billion in 1985 to a deficit of $15.2 billion in 2017, the deficit in electrical components grew from a deficit of $211 million in 1985 to a deficit of $12.7 billion in 2017, and the deficit in transmission and powertrain parts grew from a deficit of $60 million in 1985 to a deficit of $3.9 billion in 2017.[120]

[120] *Ibid.*

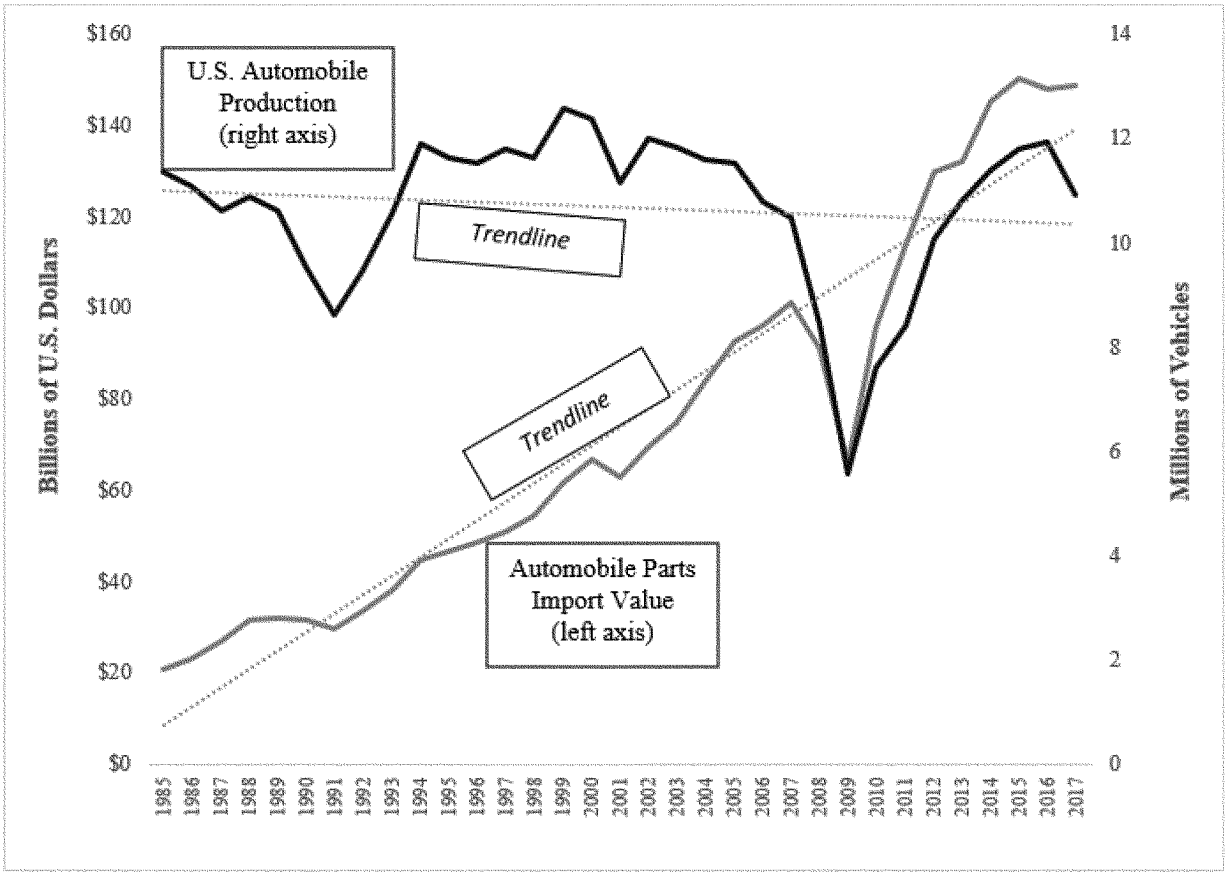
Figure 24: U.S. Trade Deficit in Automobile Parts by Type



Source: Department of Commerce, Census Bureau.

Further, a comparison of the increase in U.S. imports of overall automobile parts to the decline in U.S. automobile production, as shown in Figure 25, confirms that U.S. automobile producers have become increasingly reliant on foreign-produced parts. As technological innovations in engines, transmissions and electrical components are critical for U.S. defense capabilities as set forth in Section VI.C, the United States' increasing dependence on imports—and thereby loss of the manufacturing base and related worker skills and technological know-how for cutting-edge innovations with significant military applications—poses a significant threat to national security.

Figure 25: Comparison of U.S. Automobile Parts Imports to U.S. Automobile Production



Source: Wards Intelligence InfoBank; Department of Commerce, Census Bureau.

2. U.S. Producers of Automobile Parts Are Facing Downward Pressure on Prices Due to Low U.S. Automobile Prices

As U.S. production of engines and parts, transmissions and powertrain parts, and electrical components has been negatively impacted by imports, producers—especially American-owned producers—in the U.S. market are finding it difficult to stay competitive due to escalating costs associated with technological advancements. Cost increases have been driven, in large part, by advancements in vehicle electronics, connectivity systems, safety features, advanced driver-assistance systems, and autonomous vehicle technologies.[121] To illustrate, a McKinsey study of North American automobile parts suppliers found that the aggregate average real cost of automobile parts (indexed to 2010 dollars and adjusted to compensate for inflation, productivity changes, and other macroeconomic forces) for passenger vehicles was approximately $13,400 in 2010, and is expected to rise to $15,900 by 2020, an increase of almost 20 percent. These estimates also indicate that parts costs increased to approximately $14,100 in 2013 and $15,100 in 2017 (with an overall 13 percent increase from 2010).[122] This presents a significant problem to automobile parts suppliers, as they have been unable to increase prices to help compensate for higher costs. Indeed, during the same 2010 to 2017 period, the average sales price of a new automobile in the United States increased from $24,063 in 2010, to $24,454 in 2013, and to $25,366 in 2017 (a five percent increase).[123] That is to say, over the same seven-year period, the average price of a vehicle increased far less than the price increase associated with components. As acknowledged by the McKinsey study, ''OEMs were unable to raise prices for mass-market cars. In turn, [they] used their purchasing power to limit suppliers' abilities to increase prices, even in the face of higher input costs,'' thereby eroding automobile parts producers' profitability.[124]

Further, for automobile producers' U.S. operations, [TEXT REDACTED] from 2013 to 2017, while the average revenue earned per vehicle [TEXT REDACTED].[125] For American-owned automobile producers in particular, [TEXT REDACTED].[126] During the 2013 to 2017 period, American-owned

[121] Jim Irwin, *EV, AV Spending in Slowing Market Points to 'Pile Up,'* WardsAuto, July 30, 2018, *https://www.wardsauto.com/alternative-propulsion/ev-av-spending-slowing-market-points-pile?NL=WAW-04&Issue=WAW-04_20180730_WAW-04_297&sfvc4enews=42&cl=article_1_b&utm_rid=CPENT000004033195&utm_campaign=19649&utm_medium=email&elq2=017d7eb1c3c741dba293777515e91e6a.*

[122] McKinsey & Company, *The Future of the North American Automotive Supply Industry,* March 2012, *https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/automotive%20and%20assembly/pdfs/the_future_of_the_north_american_automotive_supplier.ashx;* Department of Commerce calculations.

[123] Wards Intelligence InfoBank.

[124] McKinsey & Company, *The Future of the North American Automotive Supplier Industry, supra.*

[125] U.S. Producers' Survey Responses, Question 2a and Question 3.

[126] *Id.*

producer's [TEXT REDACTED]. As a result, the COGS-to-revenue ratio per vehicle [TEXT REDACTED].[127] That the average unit COGS for automobile producers in the United States [TEXT REDACTED] makes clear that American-owned producers of automobiles [TEXT REDACTED] in costs to their U.S. customers, [TEXT REDACTED].

Foreign-owned automobile producers operating in the U.S. market, where a significant volume of automobile parts are sourced abroad [TEXT REDACTED], have not experienced [TEXT REDACTED].[128] From 2013 to 2017, foreign-owned producers' average per-vehicle COGS [TEXT REDACTED], while their [TEXT REDACTED].[129] This led to an overall average COGS-to-revenue ratio [TEXT REDACTED], which means that foreign-owned producers [TEXT REDACTED].[130] Further, during the 2013 to 2017 period, foreign-owned automobile producers' [TEXT REDACTED].[131] Import prices, moreover, were [TEXT REDACTED], as noted above.

In short, [TEXT REDACTED] given that low-priced imports have prevented U.S. producers from increasing their automobile prices by a sufficient margin to offset increases in costs. Additionally, as noted, U.S. automobile producers often used their purchasing power to limit price increases (or compel price decreases) by their parts suppliers.[132]

Consequently, automobile parts are now being increasingly produced in foreign countries. As previously shown in Figures 20 through 25, automobile producers have become increasingly reliant on automobile parts imported from foreign suppliers. Furthermore, the number of automobile parts manufacturing establishments in the United States have fallen, decreasing from 5,624 in 2005 to 4,948 in 2016.[133] [TEXT REDACTED].[134] Domestic demand for automobile parts clearly exists, but the contraction of the automotive parts manufacturing base in the United States has impeded the growth of related R&D investments by American-owned firms in technological advancements that are essential for U.S. defense capabilities.[135]

C. Domestic Manufacturing and Domestic R&D in Technologies for Engines, Transmissions, and Electrical Components Are Necessary for National Security

As previously noted, the automotive industry is a key driver of innovation for the U.S. military and develops state-of-the-art technologies, from autonomous vehicles equipped with navigation systems that enable them to maneuver over dangerous terrain to lighter and more powerful fuel-efficient vehicles. Given that many of the technological advancements in military vehicle connectivity, electrification, lightweighting, and autonomous driving are first developed through R&D in the commercial automotive sector in the United States, it is imperative that related R&D remain within the United States, be conducted by American-owned firms, and that the United States Government take measures to secure the long-term viability of domestic R&D in the automotive sector.

As a general matter, it is well understood that globalization of the automobile sector has decentralized production such that decoupling R&D from manufacturing has become possible, allowing producers to seek manufacturing investments in areas where production costs are lowest and to focus R&D investments in locations where specific technological progress is being made.[136] To the extent R&D is removed from manufacturing, it occurs in areas where technology has matured, the value of integrating product design with manufacturing is low, and the product has little bearing on national security. On the other hand, manufacturers tend to locate R&D in close proximity to manufacturing facilities when the technology is emerging or product-specific.[137]

Further, where technology is important to product innovation and R&D directly impacts national security capabilities, it is essential that R&D remain in each producer's home country, so as to minimize knowledge and innovation outflows that could undermine a nation's competitive advantage.[138] In the automotive sector, co-locating the manufacture of automobiles and automobile parts with related R&D increases the rate of efficiency in the adoption of technological gains. Advancements in vehicle lightweighting, connectivity, electrification and autonomous driving require highly specialized and innovative manufacturing processes, such that R&D is optimized when located in close proximity to manufacturing facilities.[139] As complexities in product design increase and the market demands faster innovation, R&D proximity facilitates the rapid development of product life cycles and gives manufacturers sufficient flexibility to capture R&D breakthroughs.[140] For technologically advanced products, ''even minor changes in the [manufacturing] process can have a huge impact on the product, the value of closely integrating manufacturing and R&D is high, and the

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] *Id.*.

[132] *See* McKinsey & Company, *The Future of the North American Automotive Supplier Industry, supra.*

[133] U.S. Census Bureau, Business Patterns, NAICS code 3363.

[134] U.S. Producers' Survey Responses, Questions 4–6.

[135] John Moavenzadeh, *Offshoring Automotive Engineering: Globalization and Footprint Strategy in the Motor Vehicle Industry,* Dec. 1, 2006, *https://www.nae.edu/File.aspx?id=10284&v=79e01bce.* The erosion of the U.S. automobile parts supplier base has been a decades-long trend. In 1998 the New York Times reported that from 1978–1998 GM's Delphi division had built over 50 manufacturing plants in Mexico. A major factor listed for the shift of parts assembly was lower costs (derived from lower labor costs), with some U.S. workers earning $22 an hour in 1998 being replaced by Mexican workers earning $1 to $2 an hour. Sam Dillon, *A 20-Year G.M. Parts Migration To Mexico,* New York Times, Jun. 24, 1998, *https://www.nytimes.com/1998/06/24/business/international-business-a-20-year-gm-parts-migration-to-mexico.html.* In 2006, Delphi announced the closing or sale of 21 out of 29 of its U.S. automobile parts plants, with new operations being announced in Mexico and China. Kate Lithicum, *A tale of two cities: What happened when factory jobs moved from Warren, Ohio, to Juarez, Mexico,* Los Angeles Times, Feb. 17, 2017, *http://www.latimes.com/world/mexico-americas/la-fg-mexico-us-factories-20170217-htmlstory.html.* In 2007, TRW's Chief Operations Officer discussed in an interview the firm's ongoing plans to shift production to low-cost countries. At that time 37–38 percent of the firm's operations were in low cost countries, but TRW had a five-year plan to move to 50 percent sourcing from those countries. Douglas Bolduc, *TRW Plan: Buy More Parts from Low-Cost Countries,* Automotive News, May 21, 2007, *http://www.autonews.com/article/20070521/SUB/70516021/trw-plan%3A-buy-more-parts-from-low-cost-countries.* By 2013, Automotive News reported seven of the largest North American automobile parts suppliers were expanding their operations in Mexico. China was also listed by the large supplier companies as a key destination for new operations. David Sedgewick, *Global Industry Craves Megasuppliers,* Automotive News, Jun. 17, 2013, *https://www.autonews.com/assets/PDF/CA89220617.PDF.*

[136] *Global Location Strategy for Automotive Suppliers,* KPMG International, Feb. 21, 2009, *https://www.kpmg.de/docs/Global_Location.pdf.*

[137] *See* Gary P. Pisano and Willy C. Shih, *Does America Really Need Manufacturing,* Harvard Business Review, March 2012, *https://hbr.org/2012/03/does-america-really-need-manufacturing; The Proximity of Manufacturing Increases the Rate of R&D Efficiencies,* Aalto University, Mar. 15, 2017, *https://phys.org/news/2017-03-proximity-efficiencies.html.*

[138] *Id.;* Juan Alcacer and Minyuan Zhao, *Local R&D Strategies and Multi-Location Firms: The Role of Internal Linkages,* Harvard Business School Working Paper, 2010, *https://www.hbs.edu/faculty/Publication%20Files/10-064.pdf.*

[139] *Supra* n. 137.

[140] European Commission, *Study on the Relationship Between the Localisation of production, R&D and Innovation Activities,* Final Report ENTR/90/PP/2011/FC, Sep. 2014, *http://ec.europa.eu/DocsRoom/documents/6958/attachments/1/translations/en/renditions/native* at 30, 50.

risks of separating them are enormous.'' [141]

Moreover, it is important that R&D be conducted by American-owned firms in the United States, given the national security implications of advanced vehicle technologies with military applications. Indeed, all major automobile-producing countries utilize export control laws to restrict the transfer of military technologies to foreign entities, whether within or outside their domestic borders, which means that the United States may not be able to rely on technologies developed in allied countries to give its military a competitive edge. Even for R&D conducted in the United States, it is important that the R&D be conducted by American-owned firms to reduce reliance on foreign-owned companies' domestic R&D investments and ensure access in time of national emergency to the necessary intellectual property (''IP''). Although the DOD utilizes R&D conducted by U.S. operations of foreign-owned firms, this R&D may not be available in a time of national crisis. Indeed, foreign-owned manufacturers are unlikely to share cutting-edge IP with their American competitors, especially technologies in which they have invested billions of dollars for commercial reasons. Further, in a time of war (or other crisis) their home governments may also prevent them from providing DOD with access to innovative technologies.

The interdependence between domestic manufacturing and American-owned R&D explains precisely why imports of automobile parts pose a threat to U.S. national security. Dependence on imports over time leads to the loss of domestic manufacturing competence and related R&D, and therefore the deterioration of the ability to lead advancements in innovation that are important for military needs.

1. The U.S. Military Relies on the Domestic Automotive Sector for Technological Advancements

According to the DOD, technological advancements in U.S. military automotive programs are driven by domestic innovations in engine, transmission and electrical component technologies, and the U.S. military relies on rapid application of U.S. commercial breakthroughs to gain competitive military advantages.[142] For example, the National Advanced Mobility Consortium (NAMC) recently awarded a $47 million contract to Cummins and Achates Power to develop a supercharged turbo diesel engine for the Bradley and Next Generation Combat Vehicle under the Advanced Combat Engine (''ACE'') program.[143] This program builds on the 60 years of experience that Cummins Diesel has manufacturing commercial turbo diesel engines.[144] It also provides an opportunity for the commercial supplier to incorporate technologies that focus on military specifications such as engine thermal management, power density, and fuel efficiency into commercial automobiles.

Likewise, the U.S. military is exploring power options such as hybrid electric engines and hydrogen fuel cells, finding that quiet new engine designs promise additional military benefits beyond breakthroughs in fuel consumption, range and reliability. The U.S. military has long sought to reduce its dependence on fossil fuels to lower costs and the risks associated with producing and transporting combustible fuels through war zones.[145] Accordingly, the U.S. military has been exploring hybrid electric drive systems that combine an electric drive with a combustion engine for greater efficiency. These technologies have been the subject of years of effort and billions of dollars of research by the passenger vehicle industry. Engines, both gas and electric, and the drivetrain parts required to integrate them into an efficient combination, are all critical automobile parts technologies that must be retained for both R&D and production in the United States.

In fuel cells, General Motors Global Fuel Cells Activities Division is working with the U.S. Army Tank Automotive Research, Development and Engineering Center (''TARDEC'') [146] to develop a hydrogen fuel cell-powered light-duty utility truck (''ZH2''). This vehicle, based on a Chevy Colorado light truck design, is powered by a fuel cell and a battery that has near silent operation, gives off less heat, and provides water as a by-product for use in the field. This work builds on GM's fuel cell experience via their Project Driveway, a 119-vehicle fleet driven by more than 5,000 people in a multi-year fuel cell experience program accumulating 3.1 million miles of hydrogen fuel cell testing. The Army is in the process of evaluating the truck for potential use in military operations.[147]

Along with engines, transmission technology is also critical to military vehicles. For example, the Advanced Vehicle Power and Technology Alliance (''AVPT''), which aligns experts from the U.S. Department of Energy and the Department of the Army, has specifically identified advanced combustion engines and transmissions as products of special interest for collaboration.[148] The U.S. military has found it challenging to source transmissions with sufficient performance capabilities for the extreme demands and conditions under which military vehicles must operate.[149] Transmissions for modern military vehicles must be engineered to adapt and operate efficiently, offering peak performance in wheeled military applications. Military transmissions must reliably deliver precise propulsion control, high productivity and efficiency, and reliable operation. The U.S. commercial automotive industry has made significant progress in these performance capabilities, and adaptation of advancements in automotive transmission technology for military applications is common. Indeed, the U.S. automotive industry's move away from manual to automatic transmissions has been closely followed by the military, with automatic transmissions now routinely incorporated in military tactical vehicles.

Similarly, the DOD's TARDEC has evaluated various suppliers including

[141] *Supra* n. 137.

[142] The Department of Commerce's consultations with Department of Defense.

[143] Kylie Veleta, *Cummins to Design Combat Engines That Elude the Enemy,* Inside Indiana Business with Gerry Dick, Feb. 15, 2018, *http://www.insideindianabusiness.com/story/37513588/cummins-to-design-combat-engines-that-elude-the-enemy.*

[144] Cummins, ''*Holset Turbo Technologies, Innovative Engineering, Absolute Reliability,*'' *https://www.cummins.com/components/holset-turbo-technologies.*

[145] The Department of Commerce's consultations with Department of Defense.

[146] The U.S. Army Tank Automotive Research, Development and Engineering Center's (TARDEC) mission is to ''develop, integrate and sustain the right technology solutions for all manned and unmanned Department of Defense (DoD) ground systems and combat support systems to improve Current Force effectiveness and provide superior capabilities for the Future Force,'' *https://tardec.army.mil/#content/4.*

[147] *Mission-Ready Chevrolet Colorado ZH2 Fuel Cell Vehicle Breaks Cover at U.S. Army Show, Modified Midsize Pickup Goes into Extreme Military Field Testing in 2017,* GM Corporate Newsroom, Oct. 3, 2016, *https://media.gm.com/media/us/en/gm/news.detail.html/content/Pages/news/us/en/2016/oct/1003-zh2.html.*

[148] Chris Williams, *DoE, Army Alliance Underlines Achieving Energy Security,* Tank Automotive Research, Development and Engineering Center, Aug. 1, 2011, *https://www.army.mil/article/62727/doe_army_alliance_underlines_achieving_energy_security.*

[149] John Tasdemir, *Ground Vehicle Systems Engineering and Technology Symposium, GVPM Powertrain Overview,* Aug. 11, 2011, *http://www.dtic.mil/dtic/tr/fulltext/u2/a547261.pdf.*

Allison, L3, and SAPA [150] to provide steering transmissions to support the next generation Bradley Fighting Vehicle.[151] The goal of the Advanced Powertrain Initiative is to test the performance of a 32-speed transmission. Although defense is the dominant market for these steering transmissions, the next generation transmission depends on innovation developed in standard transmissions and steering transmissions used in the commercial sector. Many suppliers supporting defense applications in this segment participate in commercial activity, including:

- *First tier suppliers:* Allison, L3, Twin Disc, General Engine Products
- *Sub-tier commercial suppliers for transmissions and transmission components:* ZF Friedrichshafen AG*, Valeo SA*, BorgWarner, Inc., GKN Driveline*, JATCO*, Linamar Corp.*, Schaeffler Group USA Inc.*, Brose North America, Inc.*, Powertech America, Inc.*, NSK Americas*, Johnson Electrics*

* The supplier is a U.S. affiliate of a foreign-owned parent.

Similarly, electrical equipment is critical for military vehicles. There is a large overlap in the commercial automobile control/electronics systems and the connectivity systems that are being incorporated into military vehicles. Network technology is now embedded in every new civilian vehicle, and military vehicles are increasingly becoming more network intensive. Military vehicles now routinely utilize the Controller Area Network (''CAN'') technology developed for the commercial vehicle world, which allows remote monitoring of the vehicle's performance and need for maintenance. Military vehicles are also connected to operational or mission networks that link vehicle computers, data links, radios, vision, and navigation systems directly involved in missions. These networks are similar in nature to advanced connected networks that are now routinely available in new passenger cars and trucks.[152]

Further, semiconductors are vital to U.S. national security as they power many of the high-tech systems used by the U.S. military,[153] including field communications, transportation systems, and various weapon systems and platforms.[154] Specific and unique U.S. military semiconductor requirements include radiation-hardened semiconductors for satellites and space operations, high performance converters for radio frequency communication systems, special processors for radar systems, and advanced imagers.[155] As with the transmission sector, there are many suppliers that overlap with the commercial sector, including:

- *First tier suppliers:* Harris, Telephonics Corporation, DRS*, Rockwell Collins.
- *General suppliers of semiconductors:* Intel, Micron, Qualcomm, AMD, Applied Materials, Cadence, Synopsys.[156]
- *Sub-tier commercial suppliers for communication systems/components to North America:* Denso International America Inc.*
- *Sub-tier commercial suppliers for navigation system/components to North America:* Panasonic Automotive Systems Co. of America*, Mitsubishi Electric Automotive America Inc.*, Alpine Electronics of America Inc.*, Pioneer Automotive Technologies Inc.*
- *Sub-tier commercial suppliers for sensors to North America:* Panasonic Automotive Systems Co. of America*, Valeo Inc.*, Flex Ltd.*, Infineon Technologies North America Corp.*, Stoneridge Inc.
- *Sub-tier commercial suppliers for electronics to North America:* Continental Automotive Systems U.S. Inc. (safety and powertrain)*, Robert Bosch (electrical devices, electronics & steering systems)*, Aisin World Corp. of America (electronics)*, Hyundai Mobis (electronics)*, Autoliv North America (safety electronics)*, Sumitomo Electric Wiring Systems Inc. (electronics systems)*, Yanfeng Automotive Interiors (electronics)*, Brose North America Inc. (electronics)*, Magneti Marelli Holding USA (electronics)*, Eberspaecher North America Inc. (electronics)*.

* The supplier is a U.S. affiliate of a foreign-owned parent.

In addition to providing unique product development and performance enhancements for key products such as engines, transmissions and electrical components, the U.S. defense sector relies on the automotive industry more broadly. The automotive sector provides unique innovation to the defense sector in various areas, including manufacturing processes, R&D, and use of new materials.

Importantly, the defense industrial base is also dependent on the commercial scale of the automotive sector for critical commodities and capabilities.[157] Yet, the continued offshoring of key automotive manufacturing and resulting loss of scale to support U.S. operations leaves the military at risk of not having supply chains in the United States for critical equipment. Additionally, the military relies not only on technology and innovations from the U.S. automobile industry, but also on the technical skills and know-how of its workforce as the commercial sector is a key recruiting ground for defense industry manufacturers.[158]

The broad-scale overlap between commercial and defense R&D activities underscores the interdependence between the commercial automobile industry and the military sector:

[150] Allison, L3, and SAPA are leading global suppliers of transmissions, other automobile parts and defense technologies.

[151] Ashley Tressel, *Race to replace Bradley transmissions stirs up defense industrial base issues,* Inside Defense, June 22, 2018, *https://insidedefense.com/share/196943.* A foreign-owned supplier won this competition, indicating the needs to better support the competitiveness of American-owned manufacturers.

[152] Richard Wilson, *Military Vehicles in High Speed Data Connection,'' ElectronicsWeekly.com,* May 21, 2013, *https://www.electronicsweekly.com/market-sectors/military-aerospace-electronics/military-vehicles-in-high-speed-data-connection-2013-05/.*

[153] Michaela D. Platzer and John F. Sargent Jr., *U.S. Semiconductor Manufacturing: Industry Trends, Global Competition, Federal Policy,* Congressional research Service, Jun. 27, 2016, *https://fas.org/sgp/crs/misc/R44544.pdf* at 21; Brig. Gen. John Adams, *America's Semiconductors Supply Chain Faces Big Cybersecurity Risks,* Alliance for American Manufacturing Blog, Mar. 23, 2017, *http://www.americanmanufacturing.org/blog/entry/americas-semiconductors-supply-chain-faces-big-cybersecurity-risks. See also* Falan Yinug, *How U.S. Semiconductor Technology Strengthens Our Military on the Battlefield,* Semiconductor Industry Association Blog, Jan. 26, 2016, *http://blog.semiconductors.org/blog/how-us-semiconductor-technology-strengthens-our-military-on-the-battlefield.*

[154] Dave Chesebrough, *Trusted Microelectronics: A Critical Defense Need,* National Defense, Oct. 31, 2017, *http://www.nationaldefensemagazine.org/articles/2017/10/31/trusted-microelectronics-a-critical-defense-need.*

[155] For example, semiconductors are key to the land-based weapons system that the United States uses to defend airspace against aircraft, cruise missiles, drones, and ballistic missiles. Joe Pappalardo, *How Patriot Missiles Will Stay a Step Ahead of the Enemy,* Popular Mechanics, Aug. 27, 2015, *https://www.popularmechanics.com/military/research/a17100/patriot-missiles-radar-gallium-nitride/;* NDIA Trusted Microelectronics Joint Working Group, *Future Needs & System Impact of Microelectronics Technologies,* Jul. 2017, *https://www.intrinsix.com/hubfs/Premium_Content/trusted-asic-design/Future_Needs_and_System_Impact_of_Microelectronics_Technologies.pdf.*

[156] Electronic systems for automotive purposes account for 9 percent of total global electronic system production (2017 estimate), after communications, computer, industrial/medical/other, and consumer purposes. This is significant for semiconductor suppliers, as their products are required for many of these automotive systems. *Automotive Electronic Systems Growth Strongest Through 2021,* IC Insights, Nov. 8, 2017, *http://www.icinsights.com/news/bulletins/Automotive-Electronic-Systems-Growth-Strongest-Through-2021/.*

[157] The Department of Commerce's consultations with Department of Defense.

[158] *Id.*

• The DOD partners with the commercial automotive sector to conduct pre-competitive research in areas that ultimately prove to have commercial and defense applications. For example, the DOD is a partner in LIFT (Lightweight Innovations for Tomorrow, an industry-led, government-funded consortium), along with General Dynamics and the Original Equipment Supplier Association, which represents commercial automobile parts suppliers. LIFT is ''part of a national network of research institutions and industrial companies geared toward advancing America's leadership in manufacturing technology.'' [159]

• University Centers of Excellence (''COEs'') seek to expand the frontiers of knowledge in research areas where the Army has enduring needs. COEs couple state-of-the-art research programs at academic institutions with broad-based graduate education programs to help increase the supply of scientists and engineers in automotive and rotary wing technology.[160]

• DOD's TARDEC [161] and GM have enjoyed a successful fuel cell-focused collaborative research relationship for years, beginning with a Cooperative Research and Development Agreement to test fuel cell stacks. This relationship grew through the development of the Chevrolet Colorado ZH2 light truck, which debuted in 2016 and was tested and demonstrated by the U.S. Army over the next year. GM presented SURUS (a hydrogen fuel cell vehicle) in 2017 at the annual meeting of the Association of the United States Army.[162]

• The Automotive Research Center, a U.S. Army Center of Excellence for Modeling and Simulation of Ground Vehicles led by the University of Michigan, partners with the following government and private sector entities for R&D advancements:[163]

Ansys, Inc	*AVL North America, Inc	BAE Systems.
*Ballard Power Systems, Inc	*BETA CAE Systems USA	Boeing Research and Technology.
*Robert Bosch	Caterpillar	*Daimler.
Detroit Diesel Corporation	*FEV Group	*Fiat Chrysler.
Ford Motor Company	General Dynamics Land Systems	GE Global Research.
General Motors Corporation	*HBM nCode	*Henkel North America.
Quantum Signal LLC	RAMDO Solutions	*Rolls-Royce North America.
Soar Technology	*Ultra AMI	*Yokohama Rubber, Inc.
Argonne National Lab	Army Research Lab	Cold Regions Test Center.
Environmental Protection Agency (EPA)	National Aeronautics and Space Administration (NASA) Jet Propulsion Lab.	National Institute of Standards and Technology, U.S. Department of Commerce.
National Renewable Energy Lab	Oak Ridge National Lab.	

*The supplier is a U.S. affiliate of a foreign-owned parent.

These examples illustrate the intense level of cooperation between the commercial and military vehicle sectors and the importance of commercial R&D spending in the United States that supports U.S. military leadership.

Finally, while the U.S. military presently benefits from R&D investments by both American-owned and foreign-owned companies in the United States, it is important to underscore that, in the time of national emergency, foreign-owned subsidiaries may not be willing or able to continue their R&D collaboration with the U.S. Government. Nor would it be logical to expect foreign R&D enterprises in the United States to share their research and patented technology with American-owned competitors. It is for this reason that innovation by American-owned firms is essential to U.S. national security and, as explained in the following section, the overall weakening of the United States' automotive industry adversely impacts American-owned firm's ability to invest in R&D in order to maintain leadership in technologies that have important military applications.

2. Growth of American-Owned R&D for Critical Automobile Parts Is Essential To Strengthen U.S. National Security

The 2018 U.S. National Defense Strategy explicitly states that ''[n]ew commercial technology will change . . . the character of war'' and that ''many technological developments will come from the commercial sector.'' [164] In describing necessary tactics to solidify the U.S. military's competitive advantage, the National Defense Strategy emphasizes that the DOD must invest broadly in the ''rapid application'' of commercial breakthroughs.[165] Comparing the [TEXT REDACTED] establishes the importance of maintaining a robust automotive R&D presence in the United States. In 2017, foreign- and American-owned automobile producers spent [TEXT REDACTED] on R&D in the United States, with American-owned producers accounting for [TEXT REDACTED] of that total, compared to [TEXT REDACTED] spent on R&D by armored vehicle producers.[166] [TEXT REDACTED].[167] Therefore, U.S. armored vehicle producers, and by extension the U.S. military, depend on the continued U.S. leadership and innovation of the commercial automotive sector.

Given the importance of automobile engines, transmissions and electrical systems to technological advancements in military transportation vehicles, and given the importance of co-locating R&D and manufacturing for these technologies, it is imperative that the United States maintain and grow a robust commercial automobile and automobile parts industry. Designing and producing automobile parts is a massive engineering challenge, which is why automobile producers globally continue to increase spending on R&D. An automobile purchased today is the product of years of R&D investments. Typically, it takes five years or more for

[159] LIFT, *Manufacturing USA, https://lift.technology/manufacturingusa/.*

[160] John F. Sargent Jr., *Defense Science and Technology Funding,* Library of Congress, Congressional Research Service, R45110, Feb. 21, 2018, *https://crsreports.congress.gov/product/pdf/R/R45110.*

[161] TARDEC, *https://tardec.army.mil/.*

[162] Douglas Halleaux, *TARDEC, GM bring SURUS to Smithsonian and SOFIC,* Defense Visual Information Distribution Service, U.S. Army Tank Automotive Research Development & Engineering Center, *https://www.dvidshub.net/news/277762/tardec-gm-bring-surus-smithsonian-and-sofic.*

[163] Automotive Research Center, Industry Partners, *http://arc.engin.umich.edu/about/industry-partners.html.*

[164] Department of Defense, *Summary of the 2018 National Defense Strategy of the United States of America,* Jan. 2018, *https://dod.defense.gov/Portals/1/Documents/pubs/2018-National-Defense-Strategy-Summary.pdf* at 3.

[165] *Id.* at 7.

[166] U.S. Producers' Survey Responses, Question 10a.

[167] *Id.*

a technology or a new vehicle model to go from design to testing to production and sale. Today's high-tech vehicle is comprised of as many as 15,000 parts all performing specialized functions in carefully designed ways.[168] The stakes for keeping pace on the development of technologically advanced and efficient engines, advanced powertrains, and better sensors are intense, and the advent of new technologies is forcing companies to augment R&D spending to remain competitive. The long lead-times for bringing technology to market and a reliance on imported automobile parts increases the vulnerability of the United States.

As most automotive R&D is focused on new vehicle design and testing, significant money is spent on the development of engines, transmissions, and electrical equipment technologies that have national security applications. Yet American-owned automobile producers have lagged behind their foreign counterparts in automotive R&D spending. Table 13 shows that, in 2017, American-owned producers represented 20 percent of global R&D spending in automobile production and seven percent of global R&D spending in automobile parts, trailing behind the EU and Japanese producers, which together controlled approximately 70 percent of global R&D spending in automobile production and nearly 90 percent in automobile parts R&D.[169] For American-owned firms, approximately [TEXT REDACTED].[170] For EU- and Japanese-owned firms, most R&D investments are made in their home countries.[171]

Table 13: 2017 Global R&D Spending by Company Nationality

R&D for Automobile Production			R&D for Automobile Parts Production		
	$ Billions	(% of Global Total)		$ Billions	(% of Global Total)
U.S.	16.2	20%	U.S.	1.4	7%
EU	32.2	40%	EU	8.6	43%
Japan	24.5	30%	Japan	9.0	45%
Korea	2.4	3%	Korea	0.6	3%
China	4.8	6%	China	0.3	2%

Source: PwC, *2017 Global Innovation 1000 Study*.

Table 14 below shows that, when global R&D is measured in relation to automobiles produced, American-owned manufacturers outspent their EU and Japanese counterparts ($1,543 by American-owned firms compared to $1,480 by EU firms, and $1,009 by Japanese firms).[172] However, this increased R&D spending per-unit highlights the impact of market share lost to automotive imports, namely that American-owned firms need to have higher per-unit R&D expenditures relative to their foreign-owned competitors in order to offset the economic impacts of lost market share. The reduced market share leads to a vicious cycle, with smaller production volumes reducing profits, which reduces funds to support overall R&D, which reduces innovation and leads to further losses of market share. China, which has the lowest per-unit R&D expenditure, often conducts R&D through joint ventures with foreign companies, lowering the amount of R&D that needs to be performed by Chinese companies. Additionally, Chinese companies are able to amortize their R&D costs over a large production base.

[168] American Automotive Policy Council, *State of the U.S. Automotive Industry 2018,* Aug. 2018, *http://www.americanautocouncil.org/sites/aapc2016/files/2018%20Economic%20Contribution%20Report.pdf* at 7.

[169] PwC, *2017 Global Innovation 1000 Study,* 2018, *https://www.strategyand.pwc.com/innovation1000#VisualTabs3.*

[170] U.S. Producers' Survey Responses, Question 10a.

[171] Stefan Di Bitonto, *The Automotive Industry in Germany,* Germany Trade & Invest, 2018, *https://www.gtai.de/GTAI/Content/EN/Invest/_SharedDocs/Downloads/GTAI/Industry-overviews/industry-overview-automotive-industry-en.pdf; see* Toyota Motor Company annual report, March 31, 2018, *https://www.toyota-global.com/pages/contents/investors/ir_library/annual/pdf/2018/annual_report_2018_fie.pdf* at 46.

[172] PwC, *2017 Global Innovation 1000 Study, supra.*

Table 14: 2017 R&D Expenditure and Production by Company Nationality

Country of Ownership	Global R&D Expenditure (Billions of $)	Global Production (Millions of vehicles)	R&D Expenditure Per Automobile Produced
United States	$16.2	10.5	$1,543
EU	$32.2	21.7	$1,480
Japan	$24.5	24.2	$1,009
South Korea	$2.4	6.1	$403
China	$4.8	17.6	$270

Source: PwC, *2017 Global Innovation 1000 Study* and Wards Intelligence InfoBank. Automobile production only includes production by those companies identified in the PwC study and includes medium and heavy duty trucks. In the case of a joint venture, the ownership is attributed to the majority partner.

The smaller production volume of American-owned manufacturers relative to global competitors hinders American manufacturers' ability to invest in R&D to the same extent as their competitors. Production must increase in order to encourage additional R&D investments, as [TEXT REDACTED].[173]

It is necessary and appropriate to focus on increased American-owned production because, with respect to the specific automotive technologies that are important for national security, American-owned producers invest R&D dollars domestically, whereas foreign-owned producers tend to invest abroad. To illustrate, in 2017 with respect to spending in the United States, [TEXT REDACTED].[174] [TEXT REDACTED].[175] [TEXT REDACTED].[176] As shown in Table 15 [TEXT REDACTED] are the most common non-U.S. locations for foreign-owned producers' R&D investments related to vehicle autonomy, connectivity, electrification, and lightweighting.[177]

Table 15: Foreign-Owned U.S. Producers' R&D Activities in Non-U.S. Locations

Type of R&D Activity	Countries of R&D Activity
Autonomy	[TEXT REDACTED]
Connectivity	[TEXT REDACTED]
Electrification	[TEXT REDACTED]
Lightweighting	[TEXT REDACTED]

Source: U.S. Producers' Survey Responses, Question 10b.

Increasing the United States' overall share of global R&D investments is essential to national security. Industry analysts expect that by 2023 about $255 billion in R&D and capital expenditures will have been spent globally on electric vehicles.[178] An additional $61 billion will be spent on autonomous vehicle technologies by the same year.[179] As advanced automotive technologies become a battleground for the industry, R&D budgets will determine how effectively automobile producers can compete and which nations will control cutting-edge technologies for both commercial and military applications.[180]

The pressure for R&D spending is so great that unprecedented sums of money are being poured into electric and autonomous vehicles years before those technologies are fully cost-competitive in the market.[181] For American-owned and foreign-owned producers in the United States, U.S. R&D activities are [TEXT REDACTED].[182]

PwC's *2015 Global Innovation 1000 Automotive Industry Findings* examined in detail the regional locations where automotive companies are conducting R&D and concluded that the automotive industry's fastest-growing and most competitive markets are now in the Asia Pacific region, dominated by China as the world's largest automobile market.[183] Even more noteworthy, the study, which examined R&D spending by location rather than by where companies were headquartered, concluded that the Asia Pacific region is increasingly where automotive innovation is concentrated.[184] From 2007 to 2015, expenditures on automotive R&D conducted in Asia increased by 70 percent, surpassing North America and Europe to become the largest regional hub of such expenditures.[185] During the same period, North American automotive R&D expenditures only increased by 23 percent.[186]

The PwC study also found that China's share of total automotive R&D

[173] U.S. Producers' Survey Responses, Questions 2b and 10.

[174] U.S. Producers' Survey Responses, Question 10a.

[175] *Id.*

[176] *Id.*

[177] U.S. Producers' Survey Responses, Question 10b.

[178] Irwin, *EV, AV Spending in Slowing Market Points to 'Pile Up,' supra.*

[179] *Id.*

[180] For example, Toyota recently announced that it will invest a record 1.08 trillion Yen in 2018 to expedite the development of autonomous driving technology, connected cars and electric vehicles, representing a 30% increase from five years earlier. *Toyota pours $22bn into R&D as Apple and Google Close in,* Nikkei Asian Review, May 10, 2018, *https://asia.nikkei.com/Business/Companies/Toyota-pours-22bn-into-R-D-as-Apple-and-Google-close-in.* Ford also recently announced that it will significantly increase its planned investments in electric vehicles to $11 billion by 2022 and have 40 hybrid and fully electric vehicles in its model lineup. The investment figure is sharply higher than Ford's previously announced target of $4.5 billion by 2020 and is mostly derived from the costs of developing dedicated electric vehicle architectures. *Ford Plans to Invest $11 Billion to Electrify Its 'Most Iconic' Vehicles,* Fortune, Jan. 15, 2018, *http://fortune.com/2018/01/14/ford-11-billion-electric-car-investment/.* And, according to BMW's 2017–18 annual report, the company planned to allocate between 6.5 and 7 percent of its 2018 gross revenue to R&D, above its usual range of 5 to 5.5 percent. *BMW to Spend Record Amount on R&D to Prepare for Electric Cars, Self-Driving Cars,* Assembly Magazine, Mar. 23, 2018, *https://www.assemblymag.com/articles/94194-bmw-to-spend-record-amount-on-rd-to-prepare-for-electric-cars-self-driving-cars.*

[181] Irwin, *EV, AV Spending in Slowing Market Points to 'Pile Up,' supra.*

[182] U.S. Producers' Survey Responses, Question 10.

[183] PwC, *2015 Global Innovation 1000 Automotive Industry Findings,* 2016, *https://www.strategyand.pwc.com/media/file/Innnovation-1000-2015-Auto-industry-findings-infographic.pdf.*

[184] *Id.*

[185] *Id.*

[186] *Id.*

had jumped dramatically from 4 percent in 2007 to 11 percent in 2015. During that same period, the U.S. share of total automotive R&D spending dropped from 29 percent to 27 percent.[187] China also replaced Germany as the second-largest importer of automotive R&D during this period.[188] According to PwC, this data reflects the shift happening in the automotive industry's center of gravity.[189] PwC's *2017 Global Innovation 1000 Study* highlights the impact of this trend, showing that of the top 20 automobile producers ranked in terms of R&D expenditures, 11 are headquartered in Asia and six are headquartered in Europe, while only 3 are headquartered in the United States (GM, Ford, and Tesla).[190]

Further, none of the top 10 automobile parts suppliers in terms of overall R&D expenditures is headquartered in the United States, while four are headquartered in Asia and the remaining six are headquartered in Europe.[191] This is problematic for the national security of the United States because the automotive industry is highly dependent on suppliers for components as well as leading-edge technological development. While U.S. automobile companies direct billions of dollars in R&D activities, this research is increasingly conducted by partner supplier companies. In fact, automobile parts manufacturers conduct about one-third of the annual $18 billion investment by the automotive industry in R&D in the United States.[192] Most automobile producers [TEXT REDACTED].[193]

[TEXT REDACTED] [194] [TEXT REDACTED].[195] As noted, automobile parts suppliers play a critical role in developing the innovations [196] that make the automotive industry high-tech,[197] and within the industry, automobile parts suppliers employ approximately 40 percent of all R&D scientists and engineers, while automobile manufacturers employ the remaining 60 percent.[198]

While American-owned producers lag behind their EU and Japanese competitors in automobile R&D, South Korean and Chinese companies are ramping up R&D expenditures and activities. Of course, there is a direct correlation between innovation and manufacturing. Japanese and EU firms are leaders in automobile production, and so their significant levels of R&D expenditures should come as no surprise. Yet, it is also important to emphasize the correlation between R&D expenditures and the low level of import penetration in each foreign country's automobile industry.[199] As discussed in Appendix F, Japanese-owned automobile producers enjoy a dominant position in their home market, as they account for nearly 100 percent of domestic vehicle production in Japan.[200] [TEXT REDACTED].[201]

Similarly, German-owned automobile producers account for 85 percent of domestic vehicle production in Germany,[202] and also rank [TEXT REDACTED].[203] The Volkswagen Group's research is based in Wolfsburg, Germany, and the company describes this development center as ''the innovation hub'' and the ''nerve centre of a global development network'' for all Volkswagen Group brands.[204]

Additionally, South Korean automobile producers account for 77 percent of domestic vehicle production in Korea,[205] and Korea ranks [TEXT REDACTED].[206]

The R&D spending by the largest foreign-owned automobile producers is a direct reflection of the advantages the firms enjoy in their protected home markets, as described in Appendix F. Volkswagen and Toyota have been among the top 20 overall R&D spenders every year since 2005,[207] and in 2017 these companies ranked first and second respectively in terms of global R&D expenditures by vehicle producers, a tremendous advantage in the highly competitive and always evolving automotive industry.[208] China is also increasing its investments in automotive R&D, reaching $12 billion in 2015.[209] Eighty-four automotive research and design centers have opened in China in the past 12 years, with the key focus of activity in cutting-edge technologies including connected vehicles and electric drivetrains.[210]

The internationalization of automotive R&D has focused primarily on local product development, and core research remains concentrated near the home bases of lead firms.[211] Offshoring of automotive R&D is, in large part, driven by the offshoring of manufacturing capabilities. As manufacturers seek to reduce manufacturing costs, production optimization compels the offshoring of R&D that follows. Data show that a country's attractiveness to R&D centers is also driven by the number of available science and engineering experts in that country.[212] For automotive R&D specifically, a 2008 PwC study and a 2012 study from the European Commission on the automotive sector both list access to talent pools and physical proximity to customers as the main factors driving R&D location

[187] *Id.*

[188] *Id.* Imported R&D refers to R&D conducted in China by companies headquartered abroad.

[189] *Id.*

[190] PwC, *The 2017 Global Innovation 1000 Study,* supra.

[191] *Id.*

[192] *MEMA Responds to Trump Administration Announcement of Additional 301 Tariffs on China,* Motor & Equipment Manufacturers Association, Jul. 11, 2018, *https://www.mema.org/mema-responds-trump-administration-announcement-additional-301-tariffs-china.*

[193] U.S. Producers' Survey Response, Question 12c.

[194] *Id.;* Department of Commerce, Bureau of Economic Analysis, 2012 Benchmark Input-Output tables. As calculated by Department of Commerce. 2012 data are the latest available.

[195] U.S. Producers' Survey Responses, Question 10a.

[196] The importance of automotive suppliers in the automotive R&D landscape is also demonstrated in future automotive technologies, and none more so than autonomous vehicle technology. For example, the Navigant Research Leaderboard, a respected and often-cited ranking system, evaluates companies developing automated driving systems. Several of the identified leaders are suppliers, including Bosch, Aptiv (formerly Delphi), Autoliv, Magna, Valeo, and ZF Friedrichshafen AG. *Navigant Research Leaderboard: Automated Driving Vehicles, https://www.navigantresearch.com/reports/navigant-research-leaderboard-automated-driving-vehicles.*

[197] Kim Hill, Bernard Swiecki, Debra Maranger Menk, and Joshua Cregger, *Just How High-Tech is the Automotive Industry?,* Center for Automotive Research, Jan. 2014, *https://autoalliance.org/wp-content/uploads/2017/01/CARReport_Just_How_High_Tech_is_the_Automotive_Industry.pdf*

[198] *Id.*

[199] David Autor, David Dorn, Gordon H. Hanson, Gary Pisano, and Pian Shu, *Foreign Competition and Domestic Innovation: Evidence from U.S. Patents,* American Economic Review: Insights, forthcoming, December 2017, *https://www.nber.org/papers/w22879.*

[200] Wards Intelligence InfoBank.

[201] U.S. Producers' Survey Responses, Question 10.

[202] Wards Intelligence InfoBank.

[203] U.S. Producers' Survey Responses, Question 10.

[204] *Research and Development,* Volkswagen, *https://www.volkswagen-karriere.de/en/unsere-bereiche/forschung-entwicklung.html.*

[205] Wards Intelligence InfoBank.

[206] U.S. Producers' Survey Responses, Question 10.

[207] PwC, *The 2017 Global Innovation 1000 Study,* supra.

[208] *Id.*

[209] Rishabh Saraswat, *Automotive R&D Ecosystem in China: The Road Ahead,* DRAUP, Dec. 14 2017, *https://draup.com/blog/automotive-rd-ecosystem-in-china-the-road-ahead/.*

[210] *Id.*

[211] Petr Pavlínek, *The Internationalization of Corporate R&D and the Automotive Industry R&D of East-Central Europe,* Economic Geography, Apr. 25, 2012, *https://www.researchgate.net/publication/260186659_The_Internationalization_of_Corporate_RD_and_the_Automotive_Industry_RD_of_East-Central_Europe* at 4.

[212] Rajesh K. Chandy, Andreas B. Eisingerich, Jaideep C. Prabhu, and Gerard J. Tellis, *Patterns in the Global Location of R&D Centres by the World's Largest Firms: The Role of India and China,* January 2010, *https://www.researchgate.net/publication/265870303_Patterns_in_the_global_location_of_RD_centres_by_the_world's_Largest_firms_The_role_of_India_and_China* at 5.

decisions.[213] Other factors included the size of the country's economy and economic growth potential.

R&D decisions are also increasingly driven by government-based initiatives to attract investment away from other automobile-producing nations. For example, the Chinese Government has increased automotive R&D in the domestic market through various incentives and restrictive investment requirements. In 2006, the Government set aside $184 million for automotive R&D support under its National High Tech R&D Program, a program designed to accelerate R&D across a range of sectors.[214] Under China's 13th Five-Year Plan (2016–2020), 20 New Energy Vehicle (''NEV'') projects were allotted around $111 million pursuant to the National Key Research and Development Program of China, a program focused on rapidly developing new energy technologies.[215]

Other traditionally low-cost countries with growing domestic markets, or within close proximity to growing markets, have also invested heavily in attracting automotive R&D. Hungary cut its corporate tax rate to 9 percent—the lowest in the EU—and introduced special tax incentives for companies with R&D investments.[216] Hungary recently invested $15 million in a test track for traditional and autonomous vehicles that it intends will become a magnet for future investment in automobile development and testing. Brazil is implementing a 14-year incentive program that will offer up to BR1.5 billion ($467.4 million) in annual tax credits for automobile producers and automobile parts manufacturers that reach certain R&D investment targets.[217]

Heavy investment in attracting R&D in new automotive technologies is also a strategy for mature automobile producing countries. In order to target new technologies and manufacturing, the South Korean Government recently agreed to invest about 2 billion Euros into hydrogen mobility (including fuel cells) over the next five years. Facilities manufacturing fuel cell vehicles and those performing related R&D will receive funding in order to reach the Government's ambitious production target of 15,000 fuel cell vehicles by 2022.[218] Additionally, fearing that the EU automobile industry could be left behind in the race to build mass market electric vehicles because of their reliance on batteries from Asia, the EU recently announced that it will offer billions of Euros of funding to companies willing to build giant battery factories in the region.[219] Individual EU countries will fund 100 percent of research.[220]

Government efforts worldwide to divert automotive R&D and related manufacturing abroad is particularly dangerous for the American-owned automotive industry. Data show that, across all industries, the United States heavily outsources R&D to other nations and that the automotive industry is a large driver of this R&D offshoring trend.[221] The offshoring of R&D activities (coupled with manufacturing) jeopardizes the ability of the U.S. automotive industry, and specifically American-owned manufacturers, to develop innovative products and deliver high-tech products and skilled workers to the industrial base, threatening technological advancements necessary for defense capabilities. Further, the offshoring of R&D and manufacturing will increasingly render the United States reliant on imported products. Conditions of competition must be improved so that American-owned automobile producers and automobile parts manufacturers are able to increase production in the United States, and thereby augment R&D levels to develop and capitalize on the latest technologies domestically.

D. Decline in Employment in the U.S. Automotive Industry

The deterioration in the competitive position of the U.S. automobile and automobile parts manufacturing industry outlined above is further evidenced by the decline in U.S. automotive industry employment, and in particular employment by American-owned firms. The U.S. automobile and automobile parts industry (American-owned and foreign-owned firms) employs approximately 798,300 workers, or approximately 6 percent of the nation's manufacturing workforce.[222] This is a significant drop from the recent peak in 2000, when the industry accounted for 291,400 automobile assembly jobs and 839,500 automobile parts manufacturing jobs.[223] The decline amounts to a loss of 332,600 manufacturing jobs, which is equivalent to approximately 7 percent of the loss in all manufacturing jobs between 2000 and 2017.[224] American-owned automobile manufacturing plants account for [TEXT REDACTED] of the overall workforce across all U.S. based-automobile plants.[225]

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[225] U.S. Producers' Survey Responses, Question 8.

[226] Bureau of Labor Statistics, Total Employment for Motor Vehicles and Motor Vehicle Parts, *supra.;* Department of Commerce, Census Bureau.

[227] Bureau of Economic Analysis, Foreign Direct Investment in the United States, Data on Activities of Multinational Enterprises; Bureau of Labor Statistics, Current Employment Statistics.

[228] U.S. automotive employment—and consequently job losses—has been spread across the United States. While Michigan continues to have the largest share at 172,000 workers, many other states are significant employers as well. Indiana currently employs 111,500 automotive workers, Ohio employs 95,300 workers, Kentucky employs

2018, *https://www.wardsauto.com/industry/brazilian-auto-industry-awaits-word-incentives.*

[218] *South Korea to Invest €2BN into Fuel Cell Vehicles, electrive.com,* Jun. 25, 2018, *https://www.electrive.com/2018/06/25/south-korea-to-invest-e2bn-into-fuel-cell-vehicles/.*

[219] Rochelle Toplensky, *EU to Offer Billions of Funding for Electric Vehicle Plants,* Financial Times, Oct. 14, 2018, *https://www.ft.com/content/097ff758-cec3-11e8-a9f2-7574db66bcd5?desktop=true.*

[220] *Id.* ''The EU's Horizon 2020 research fund has set aside €200m for battery projects; €800m is available to finance building demonstration facilities; regions looking to promote the industry can apply for the €22bn regional funds available; and the European Fund for Strategic Investment is available from the European Investment Bank to co-fund the billions of euros needed to build an EU equivalent of Tesla's 'gigafactory' in the Nevada desert.''

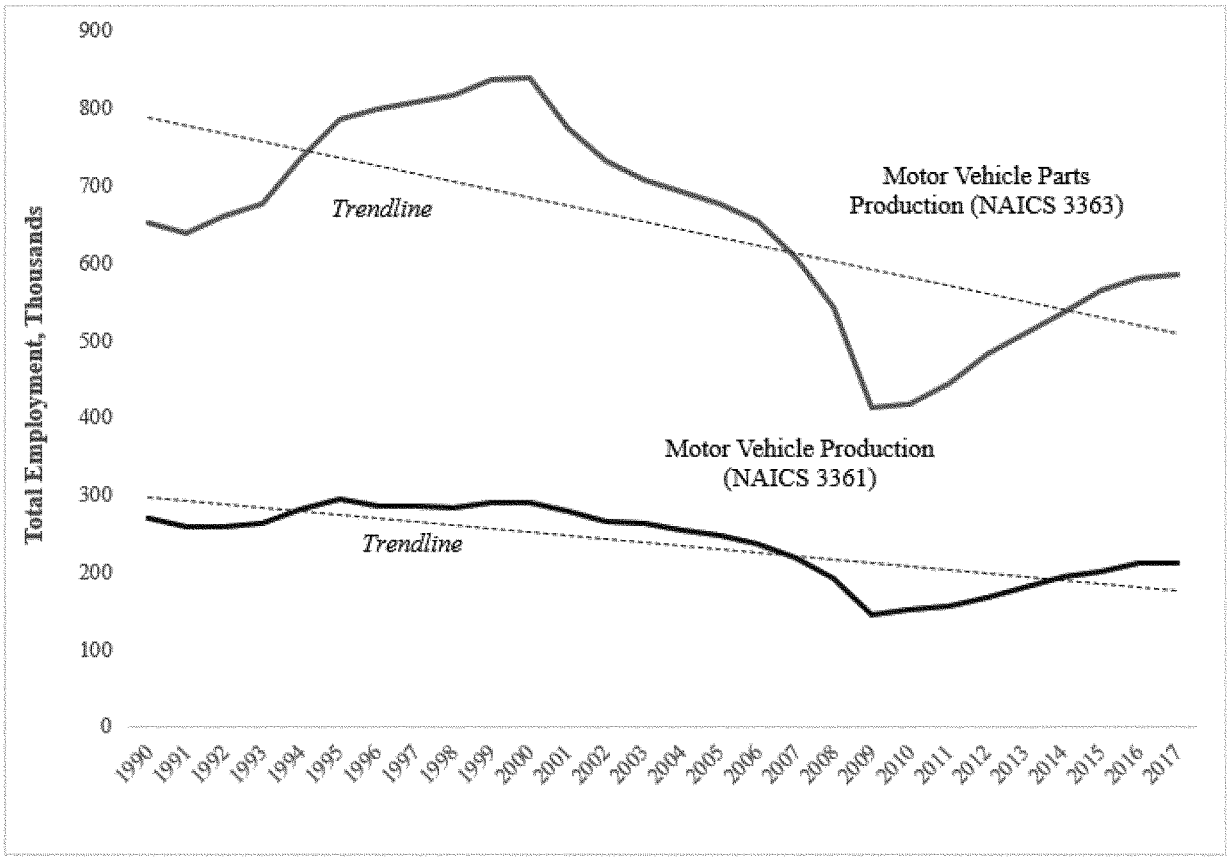
[221] J. John Wu, *Why U.S. Business R&D Is Not as Strong as It Appears,* Information Technology & Innovation Foundation, June 2018. *http://www2.itif.org/2018-us-business-rd.pdf* at 10, 13, 14.

[222] Bureau of Labor Statistics, Total Employment for Motor Vehicles and Motor Vehicle Parts, *supra.*

[223] *Id.*

[224] *Id.*

Figure 26: U.S. Employment in Automobile and Automobile Parts Production



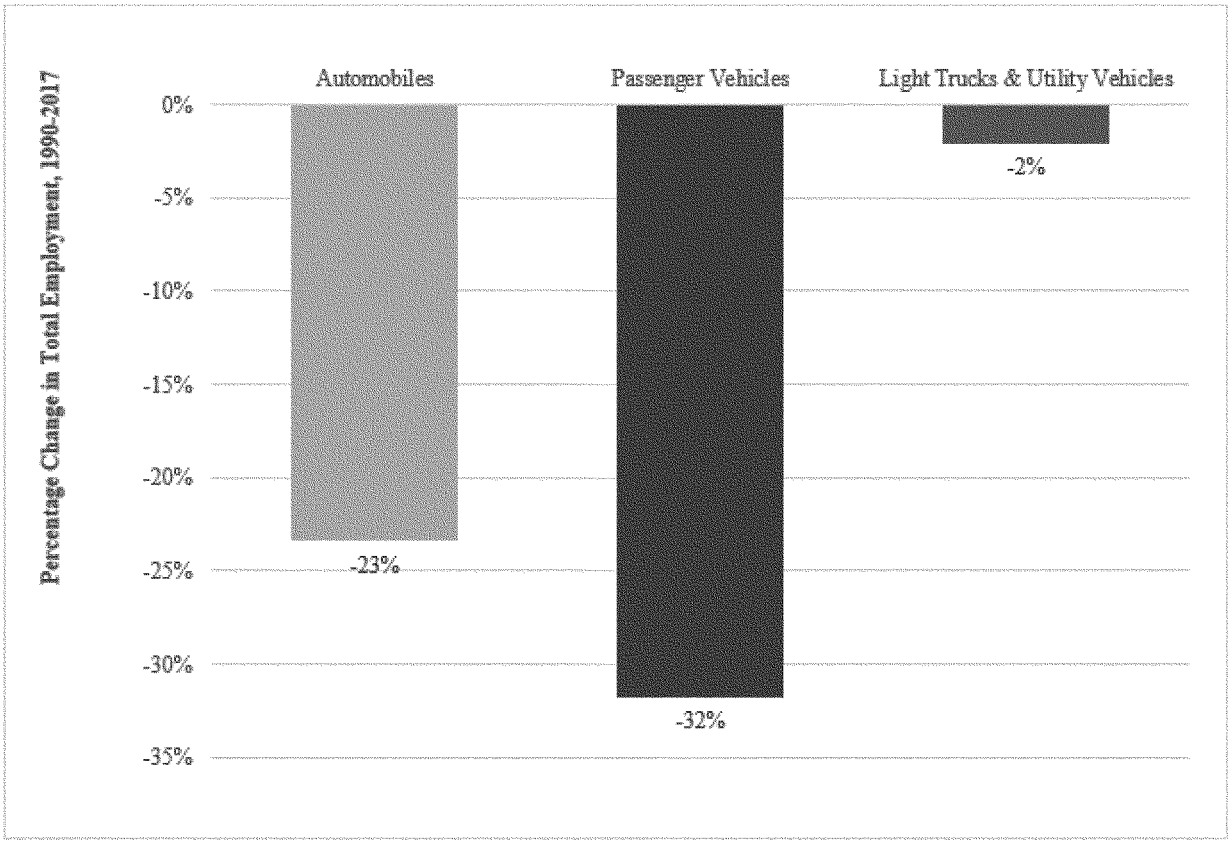
Source: Bureau of Labor Statistics

Further, as shown in Figure 27, the sharp decline in passenger vehicle manufacturing employment (sedans, SUVs, CUVs, and vans) accounts for the majority of the overall decline in automobile manufacturing jobs. This steep 32 percent decline (equivalent to 54,400 jobs) coincided with the 282 percent increase in passenger vehicle imports during this same period. Light truck imports rose more than 150 percent over the same period, contributing to job losses of two percent overall in the United States (equivalent to 1,400 jobs).[226]

[225] U.S. Producers' Survey Responses, Question 8.

[226] Bureau of Labor Statistics, Total Employment for Motor Vehicles and Motor Vehicle Parts, *supra.;* Department of Commerce, Census Bureau.

Figure 27: Change in U.S. Automobile Manufacturing Employment, 1990-2017



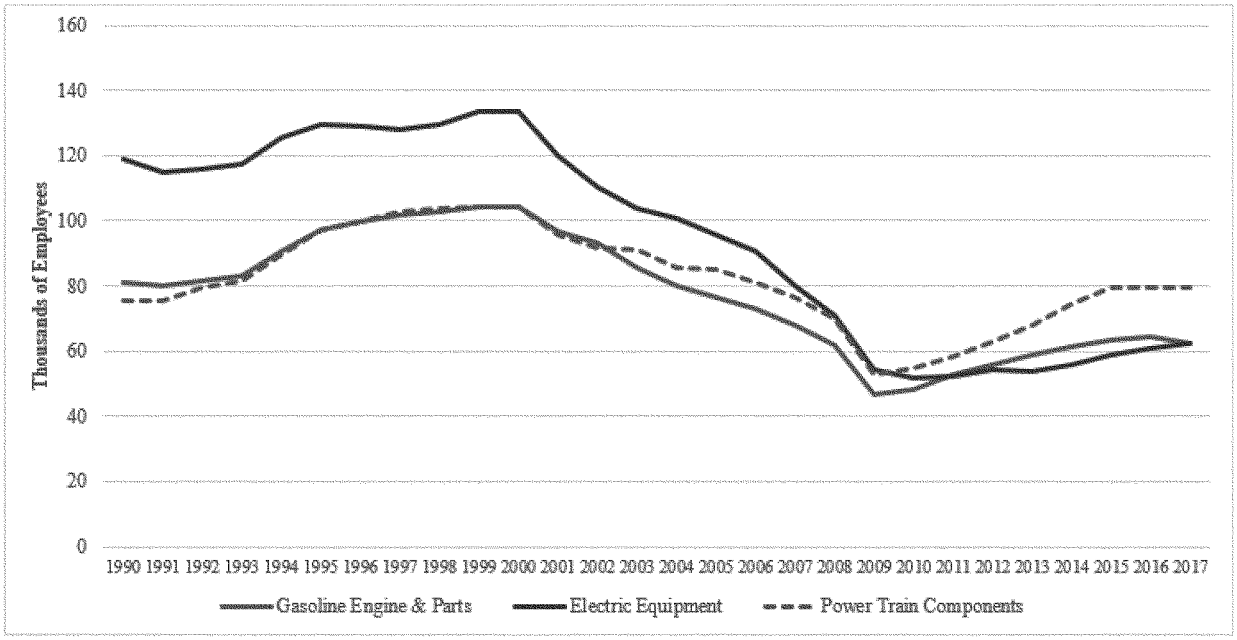
Automobiles (NAICS 33611) includes Passenger Vehicles (NAICS 336111) and Light Trucks & Utility Vehicles (NAICS 336112).

Source: Bureau of Labor Statistics. Calculated by Department of Commerce.

Figure 28 disaggregates job losses in automobile parts manufacturing by segment. Most of the decrease in automobile parts manufacturing employment is due to a 48 percent reduction in the workforce for electrical component manufacturing and a 23 percent reduction in engine and engine parts manufacturing. Although jobs in powertrain component manufacturing have increased since 2009, the number of lost jobs in that sector amount to 25,000 since 2000. Further, the skill level involved in this sector is rapidly eroding as imports of powertrain parts have caused the U.S. transmission industry to shift to assembly rather than product development and manufacturing. Overall, for parts manufacture, American-owned producers account for approximately 50 percent of the U.S.-based workforce.[227]

[227] Bureau of Economic Analysis, Foreign Direct Investment in the United States, Data on Activities of Multinational Enterprises; Bureau of Labor Statistics, Current Employment Statistics.

Figure 28: Change in U.S. Automobile Parts Manufacturing Employment



Source: Bureau of Labor Statistics.

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The loss of manufacturing jobs parallels the rate of closure of U.S. automobile manufacturing plants, in particular American-owned manufacturing plants.[228] In 1985, American-owned producers operated 62 assembly plants in the United States and produced 97 percent of the 11.4 million passenger vehicles and light trucks produced in the United States.[229] By 2000, American-owned producers were operating only 44 plants and their share of U.S. production had dropped from 97 percent to 67 percent.[230] Finally, by 2017, American-owned producers were operating only 24 assembly plants in the United States and producing only 42 percent of total U.S. production, notwithstanding the fact that overall demand for automobiles in the United States increased by 11 percent during the 1985 to 2017 period.[231] Moreover, GM recently announced its intent to close five additional plants and lay off approximately 15,000 workers in 2019.[232] In January 2019, Tesla announced a planned seven percent contraction of its workforce.[233] By contrast, foreign-owned automobile manufacturers in the United States (EU, Japanese and South Korean manufacturers), have expanded operations over the past three decades and increased the number of facilities operating in the United States from 3 facilities in 1985 to 22 in 2017.[234] As noted above, their expansion in the U.S. market has come at the expense of American-owned producers, who (as detailed in Appendix F) do not have the same market access in the EU, Japan and South Korea as their foreign counterparts do in the United States.

With the ongoing contraction of automobile and automobile parts production in the United States and resulting plant closures by American-owned firms, employment in the U.S. automotive manufacturing industry will shrink further. As noted, today's production of automobiles and automobile parts is a complex and technical process that demands a trained, skilled workforce that in many cases requires a decade or more of experience. Given that the United States needs to rely on American-owned facilities to develop cutting-edge technologies with national defense capabilities, it is imperative that a robust and skilled workforce is available to manufacture and operate those technologies. For this reason, the loss of skilled workers at American-owned plants is detrimental to America's manufacturing and innovation capabilities, and consequently America's ability to develop new and emerging technologies for military applications.

VII. Conclusion

Based on the findings in this report, the Secretary concludes that the present quantities and circumstances of imports of automobiles and certain automobile parts, specifically engines and engine parts, transmissions and powertrain parts, and electrical components as defined in Section VIII, are ''weakening our internal economy'' and threaten to impair national security as set forth in Section 232.

As discussed throughout this report, the negative impact of imports and the resulting displacement of production by American-owned automobile and automobile parts manufacturers are significant, and are increasing given that the U.S. automobile market is experiencing a decline in demand. A decline in demand is expected in the next several years due to a number of factors that impact the normal sales cycle, and many indicators point to market saturation. For example, the ratio of automobiles to households is

[228] U.S. automotive employment—and consequently job losses—has been spread across the United States. While Michigan continues to have the largest share at 172,000 workers, many other states are significant employers as well. Indiana currently employs 111,500 automotive workers, Ohio employs 95,300 workers, Kentucky employs 60,500 workers, and Alabama employs 38,300 workers, along with smaller employment in California, Missouri, Texas, New York, and Mississippi. Bureau of Labor Statistics, Total Employment for Motor Vehicles and Motor Vehicle Parts, *supra.*

[229] Wards Intelligence InfoBank.

[230] *Id.*

[231] *Id.*

[232] Eric Morath, *GM Closings a Fresh Sign of Worry for Economy,* Wall Street Journal, Nov. 26, 2018, *https://www.wsj.com/articles/gm-closings-a-fresh-sign-of-worry-for-economy-1543271097.*

[233] Tesla, *Company Update,* January 18, 2019, *https://www.tesla.com/blog/tesla-company-update.*

[234] Wards Intelligence InfoBank.

now 2:1, a record high. In addition, while approximately one quarter of the automobiles on the road are less than four years old, the average age of automobiles in the United States increased from 8.4 years in 1995 to 11.6 years in 2016,[235] and the tendency of consumers to keep automobiles longer has negatively impacted demand. (This has caused the gap between new and used automobile prices to reach record highs.) Sales peaked in 2016 at 17.5 million units, but declined to 17.1 million units in 2017, and remained at roughly the same level in 2018. A further decline in demand is expected in 2019, with interest rates projected to rise and recent reports indicating that $56.8 billion in auto loans are delinquent.[236] Equally as important, exports to foreign markets are unlikely to provide avenues for additional sales and revenue as tariff and non-tariff barriers to entry discourage U.S. automotive exports and the U.S. dollar remains strong relative to Europe, Japan, and China. Finally, employment in the automotive sector remains significantly below the industry's employment peak in 2000, impacting the ability to maintain a highly skilled workforce that is essential for national security needs.

Defense purchases alone are not sufficient to support a robust military vehicle supply chain and R&D in key automotive technologies (such as autonomous driving, vehicle lightweighting, electrification, and connectivity) that are vital to meeting the needs of national defense. To be available to meet national defense needs, American-owned automobile and automobile parts manufacturers must have a robust presence in the U.S. commercial market. Moreover, innovations generated by R&D investments are necessary for manufacturers to remain competitive in both the commercial automotive sector and the defense sector. It is that innovation capability which is now at serious risk as imports continue to displace American-owned production. An American-owned automotive industry that is not competitive in the latest technologies, nor has the ability to retain a large skilled workforce and attract the next-generation workforce, will be unable to ensure that the United States maintains the ability to produce cutting-edge technologies that are essential to America's national security.

The many factors listed in this report form the basis for the Secretary's determination that the ''displacement of domestic products by excessive imports''—in particular the displacement of automobiles and certain automobile parts manufactured by American-owned firms—is causing a ''weakening of our internal economy'' that ''may impair the national security.'' *See* 19 U.S.C. 1862(d). Therefore, the Secretary recommends that the President take corrective action. *See* 19 U.S.C. 1862(c).

VIII. Recommendation

The Secretary recommends the following actions the President could take as possible options to remove the threatened impairment of the national security:

1. Direct further discussions and negotiations to obtain agreements that address the threatened impairment of national security. Since this investigation was initiated, there have been productive discussions that could result in positive changes for the automotive industry in the United States, and the United States has signed the USMCA. If these discussions and the USMCA result in positive changes to the U.S. automotive industry, the President could determine whether those actions address the threatened impairment of the national security found in this report.

As provided in section 232(c)(3), if appropriate agreements have not been reached in a timely manner or if a negotiated agreement is not being carried out, the President could determine that further action under section 232 is necessary.

Or

2. Impose tariffs of up to 25 percent (in addition to any existing duties) on imports of automobiles and certain automobile parts (engines and parts, transmissions and powertrain parts, and electrical components) in order to increase U.S. production of automobiles and parts to a level sufficient to generate additional revenue to increase R&D investments by American-owned (as well as foreign-owned) manufacturers in the United States. Imports under USMCA Side Letters would not be subject to the tariffs.

Or

3. Impose tariffs of up to 35 percent (in addition to any existing duties) on imports of SUVs and CUVs, which will increase domestic production and generate additional revenue to increase R&D investments by American-owned (and foreign-owned) manufacturers in the United States. The Department of Commerce would work with the U.S. Customs and Border Protection on the most appropriate means to implement this option if selected. Imports under USMCA Side Letters would not be subject to the tariffs.

Exemptions

The President may wish to consider agreements that the United States has renegotiated recently in determining whether specific countries should be exempted from the proposed tariffs based on an overriding national security interest of the United States. For example, the President should consider the Republic of South Korea for an exemption based on the recently improved agreement and strong national security relationship. The Secretary recommends that any determination to exempt a specific country should be made at the outset and a corresponding adjustment be made to the final tariffs imposed on the remaining countries. Any country exempted should be placed under a quota to ensure that producers in that country do not increase exports to the United States and to prevent transshipment through that country of automobiles and automobile parts seeking to avoid tariffs. This would ensure that overall imports of automobiles and automobile parts to the United States remain at or below the level needed to enable American-owned producers to reach levels of production sufficient to increase R&D for technologies that are important to national defense.

Automobiles and Automobile Parts Subject to Tariffs Described Above

Electrical Components & Parts:
8414308030; 8414596040; 8414596540; 8414598040; 8415830040; 8507100060; 8507304000; 8507404000; 8507600010; 8507904000; 8511200000; 8511300040; 8511300080; 8511400000; 8511500000; 8511802000; 8512202040; 8512204000; 8512204040; 8512300020; 8512300030; 8512404000; 8525201500; 8525206020; 8525209020; 8525601010; 8527211015; 8527211020; 8527211025; 8527211030; 8527211500; 8527212510; 8527212525; 8527214000; 8527214040; 8527214080; 8527214800; 8527290020; 8527290040; 8527290060; 8527294000; 8527298000; 8527298020; 8527298060;

[235] U.S. Department of Transportation, Bureau of Transportation Statistics, *https://www.bts.gov/content/average-age-automobiles-and-trucks-operation-united-states.*

[236] David Harrison, *Auto Borrowing Rises as New Mortgage Loans Sag, New York Fed Says,* Wall Street Journal, Feb. 12, 2019, *https://www.wsj.com/articles/auto-borrowing-rises-as-new-mortgage-loans-sag-new-york-fed-says-11549988807?mod=searchresults&page=1&pos=7.*

8531800038; 8531808038; 8531809031; 8531809038; 8536410005; 8539100040; 9029108000; 9104004510; 8536906000; 8539100010; 8539100020; 8539100050; 8539212040; 8544300000; 9029104000; 9029204080; 9029902000; 9029908040; 9029908080; 9104002510; 9104004000

Engines & Parts: 4010101020; 4016931010; 4016931020; 4016931050; 4016931090; 8407341400; 8407341540; 8407341580; 8407341800; 8407342040; 8407342080; 8407344400; 8407344540; 8407344580; 8407344800; 8408202000; 8409913000; 8409915080; 8409915081; 8409155085; 8409919110; 8409919190; 8409919910; 8409991040; 8409999110; 8409999190; 8413301000; 8413309060; 8414593000; 8414800500

Transmission, Powertrain & Parts: 8708401000; 8708401110; 8708401150; 8708402000; 8708405000; 8708407550; 8708407000; 8708407570; 8708407580; 8708935000; 8708936000; 8708937500

Passenger Vehicles & Light Trucks 8703220000; 8703230015; 8703230022; 8703230024; 8703230026; 8703230028; 8703230030; 8703230032; 8703230034; 8703230036; 8703230038; 8703230042; 8703230044; 8703230045; 8703230046; 8703230048; 8703230052; 8703230060; 8703230062; 8703230064; 8703230066; 8703230068; 8703230072; 8703230074; 8703230075; 8703230076; 8703230078; 8703240032; 8703240034; 8703240036; 8703240038; 8703240042; 8703240050; 8703240052; 8703240054; 8703240056; 8703240058; 8703240060; 8703240062; 8703240064; 8703240066; 8703240068; 8703240075; 8703310000; 8703320010; 8703330045; 8703330060; 8703900000; 8703220100; 8703230120; 8703230130; 8703230140; 8703230160; 8703230170; 8703240140; 8703240150; 8703240160; 8703310100; 8703320110; 8703330145; 8703330185; 8703400010; 8703400020; 8703400030; 8703400040; 8703400070; 8703600020; 8703600030; 8703600080; 8703700030; 8703700070; 8703800000; 8703900100; 8704210000; 8704310020; 8704310040

Dated: November 1, 2021.

Anne Driscoll,

Acting Assistant Secretary for Industry and Analysis.

[FR Doc. 2021–24162 Filed 11–5–21; 8:45 am]

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