AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 86 Friday

No. 129 July 9, 2021

Pages 36193–36482

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 86 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**

General online information **202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Printed on recycled paper.

Contents

Federal Register

Vol. 86, No. 129

Friday, July 9, 2021

Agriculture Department
See Rural Utilities Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36249–36250
Increase in Fiscal Year 2021 Specialty Sugar Tariff-Rate Quota, 36249

Centers for Medicare & Medicaid Services
RULES
Medicare Program:
Comprehensive Care for Joint Replacement Model Three Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 36229
PROPOSED RULES
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, 36322–36437
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36281–36282

Civil Rights Commission
NOTICES
Meetings:
Tennessee Advisory Committee, 36250

Commerce Department
See International Trade Administration
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement List; Additions and Deletions, 36260–36261

Defense Acquisition Regulations System
RULES
Acquisition Regulation Supplement:
Data Collection and Inventory for Services Contracts, 36229–36237

Defense Department
See Defense Acquisition Regulations System
RULES
TRICARE:
Extended Care Health Option Respite Care, 36213–36217
NOTICES
Privacy Act; Matching Program, 36261–36262

Education Department
RULES
Final Priorities, Requirements, and Selection Criteria:
Effective Educator Development Division, 36217–36220
Final Priority and Definitions:
Teacher and School Leader Incentive Program, 36220–36222
Final Requirements:
American Rescue Plan Act Homeless Children and Youth Program, 36222–36227
NOTICES
Applications for New Awards:
Teacher and School Leader Incentive Program, 36262–36269

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Future of Energy Codes Workshop, 36269–36270

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
California; El Dorado County Air Quality Management District; South Coast Air Quality Management District, 36227–36229
NOTICES
Environmental Impact Statements; Availability, etc., 36280

Federal Aviation Administration
RULES
Airspace Designations and Reporting Points:
Missoula, MT, 36210–36212
Missoula, MT; Correction, 36212
Mountain Home, ID, 36212–36213
Airworthiness Directives:
Leonardo S.p.a. Helicopters, 36202–36205
Safran Helicopter Engines, S.A. (Type Certificate Previously Held by Turbomeca, S.A.) Turboshaft Engines, 36205–36207
Yabora Industria Aeronautica S.A. (Type Certificate Previously Held by Embraer S.A.) Airplanes, 36207–36210
PROPOSED RULES
Airworthiness Directives:
Bombardier, Inc., Airplanes, 36243–36246
Helicopteres Guimbal Helicopters, 36241–36243
NOTICES
Surrendered Supplemental Type Certificates:
Avenger Aerospace Solutions, Inc., 36315–36316

Federal Energy Regulatory Commission
NOTICES
Application:
Pacific Gas and Electric Co., 36270–36271
Combined Filings, 36276–36280
Complaint:
Arkansas River Power Authority, Delta-Montrose Electric Association, and Kit Carson Electric Cooperative, Inc. v. Tri-State Generation and Transmission Association, Inc., 36273
Environmental Assessments; Availability, etc.:
Brookfield White Pine Hydro, LLC, 36275–36276
Environmental Impact Statements; Availability, etc.:
Tennessee Gas Pipeline Co., LLC; East 300 Upgrade Project, 36277–36278

Filing:
Great River Energy, 36271–36272
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
Clines Corners Wind Farm, LLC, 36280
Duran Mesa, LLC, 36276
Red Cloud Wind, LLC, 36272–36273
Tecolote Wind, LLC, 36272
Request under Blanket Authorization:
Columbia Gas Transmission, LLC, 36273–36274
Scoping:
Mountain Valley Pipeline, LLC; Mountain Valley Pipeline Project, 36275

Federal Housing Finance Agency
RULES
Policy Statement on Fair Lending, 36199–36202

Federal Motor Carrier Safety Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers, 36317–36318
Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 36316–36317

Federal Reserve System
NOTICES
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 36281

Food and Drug Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives, 36284–36285
Food and Cosmetic Export Certificates, 36282–36283
Determination of Regulatory Review Period for Purposes of Patent Extension:
AJOVY, 36285–36286
Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal, 36283–36284

Health and Human Services Department
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health

Homeland Security Department
See Transportation Security Administration
See U.S. Citizenship and Immigration Services
See U.S. Immigration and Customs Enforcement
NOTICES
Employment Authorization for Yemeni F–1 Students Experiencing Severe Economic Hardship as a Direct Result of the Current Crisis in Yemen, 36288–36292

Interior Department
See National Park Service

Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 36318

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Certain Steel Wheels (12–16.5 inches diameter) from the People's Republic of China, 36250–36252
Chlorinated Isocyanurates from the People's Republic of China, 36253–36255
Magnesium Metal from the People's Republic of China, 36255–36256
Melamine from the People's Republic of China, 36252–36253

International Trade Commission
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Utility Scale Wind Towers from Spain, 36305–36306
Investigations; Determinations, Modifications, and Rulings, etc.:
Certain Casual Footwear and Packaging Thereof, 36303–36304
Walk-Behind Lawn Mowers from China and Vietnam, 36304–36305

Labor Department
See Occupational Safety and Health Administration

National Council on Disability
NOTICES
Meetings; Sunshine Act, 36307

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Generic Clearance to Collect Stakeholder Feedback on the Research Domain Criteria Initiative, 36287–36288
Meetings:
Center for Scientific Review, 36286–36287

National Oceanic and Atmospheric Administration
RULES
Fisheries Off West Coast States:
Coastal Pelagic Species Fisheries; Annual Specifications; 2021–2022 Annual Specifications and Management Measures for Pacific Sardine, 36237–36239
Pacific Island Fisheries:
Exemption for Large United States Longline Vessels To Fish in Portions of the American Samoa Large Vessel Prohibited Area; Court Order, 36239–36240
NOTICES
Marine Mammals and Endangered Species, 36256–36257
Meetings:
Fisheries of the South Atlantic; South Atlantic Fishery Management Council, 36257

National Park Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
National Park Service President's Park National Christmas Tree Music Program Application, 36302–36303

Nuclear Regulatory Commission
NOTICES
Meetings:
Systematic Assessment for how the NRC Addresses Environmental Justice in its Programs, Policies, and Activities, 36307–36309

Occupational Safety and Health Administration
NOTICES
Meetings:
Advisory Committee on Construction Safety and Health, 36306–36307

Patent and Trademark Office
NOTICES
Patent Eligibility Jurisprudence Study, 36257–36260

Postal Regulatory Commission
PROPOSED RULES
Public Inquiry, 36246–36248

Presidential Documents
ADMINISTRATIVE ORDERS
Hong Kong; Continuation of National Emergency (Notice of July 7, 2021), 36477–36479
Transnational Criminal Organizations; Continuation of National Emergency (Notice of July 7, 2021), 36481–36482

Rural Utilities Service
RULES
Streamlining Electric Program Procedures, 36193–36199

Securities and Exchange Commission
NOTICES
Application:
New Age Alpha Trust and New Age Alpha Advisors, LLC, 36310–36313
Self-Regulatory Organizations; Proposed Rule Changes:
NYSE Arca, Inc., 36309–36310, 36440–36476

Trade Representative, Office of United States
NOTICES
Reallocation of Unused Fiscal Year 2021 World Trade Organization Tariff-Rate Quota Volume for Raw Cane Sugar, 36315
Suspension of Action:
Enforcement of U.S. World Trade Organization Rights in the Large Civil Aircraft Dispute, 36313–36315

Transportation Department
See Federal Aviation Administration
See Federal Motor Carrier Safety Administration

Transportation Security Administration
NOTICES
PreCheck Application Program Fees, 36293–36295

Treasury Department
See Internal Revenue Service

U.S. Citizenship and Immigration Services
NOTICES
Extension and Redesignation of Yemen for Temporary Protected Status, 36295–36302

U.S. Immigration and Customs Enforcement
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Flight Manifest/Billing Agreement, 36292–36293

Unified Carrier Registration Plan
NOTICES
Meetings; Sunshine Act, 36318–36319

Veterans Affairs Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Report of General Information, Report of First Notice of Death, Report of Nursing Home or Assisted Living Information, Report of Defense Finance and Accounting Service, Report of Non-Receipt of Payment, Report of Incarceration, Report of Month of Death, 36320
Meetings:
Rehabilitation Research and Development Service Scientific Merit Review Board, 36319
Veterans' Advisory Committee on Rehabilitation, 36320

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 36322–36437

Part III
Securities and Exchange Commission, 36440–36476

Part IV
Presidential Documents, 36477–36479, 36481–36482

Reader Aids

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

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR
Notices:
Notice of July 7, 2021 .....36479, 36481

7 CFR
1710.....36193
1714.....36193
1717.....36193
1718.....36193
1721.....36193
1726.....36193
1730.....36193
1767.....36193

12 CFR
Ch. XII.....36199

14 CFR
39 (3 documents) 36202, 36205, 36207
71 (3 documents) 36210, 36212

Proposed Rules:
39 (2 documents) 36241, 36243

32 CFR
199.....36213

34 CFR
Ch.II (3 documents).....36217, 36220, 36222

39 CFR

Proposed Rules:
Ch. III.....36246

40 CFR
52.....36227

42 CFR
510.....36229

Proposed Rules:
413.....36322
512.....36322

48 CFR
204.....36229
212.....36229
252.....36229

50 CFR
660.....36237
665.....36239

Rules and Regulations

Federal Register
Vol. 86, No. 129
Friday, July 9, 2021

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

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

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Parts 1710, 1714, 1717, 1718, 1721, 1726, 1730, and 1767

[RUS–21–ELECTRIC–0003]

RIN 0572–AC53

Streamlining Electric Program Procedures

AGENCY: Rural Utilities Service, U.S. Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: The Rural Utilities Service (RUS), a Rural Development agency of the United States Department of Agriculture (USDA), is revising several regulations to streamline its procedures for Electric Program borrowers, including its loan application requirements, approval of construction work plans, contract bidding procedures, contact approval procedures, system operation and maintenance reviews, long-range engineering plans and system design procedures. Additionally, unnecessary sections in the regulations will be removed.

DATES: This rule is effective September 7, 2021.

FOR FURTHER INFORMATION CONTACT: Luis Bernal, Deputy Assistant Administrator, Office of Customer Service and Technical Assistance, Rural Utilities Service, U.S. Department of Agriculture, STOP 1569, 1400 Independence Ave. SW, Washington, DC 20250–0787, telephone: (202) 720–1900. Email: *RUSElectric@usda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Rural Development is a mission area within the U.S. Department of Agriculture (USDA) comprising the Rural Utilities Service, Rural Housing Service, and Rural Business-Cooperative Service. Rural Development's mission is to increase economic opportunity and improve the quality of life for all rural Americans. Rural Development meets its mission by providing loans, loan guarantees, grants, and technical assistance through numerous programs aimed at creating and improving housing, business, and infrastructure throughout rural America. The Rural Utilities Service (RUS) loan, loan guarantee, and grant programs act as a catalyst for economic and community development. By financing improvements to rural electric, water and waste, and telecommunications and broadband infrastructure, RUS also plays a significant role in improving other measures of quality of life in rural America, including public health and safety, environmental protection and culture and historic preservation.

RUS Electric Program loans, loan guarantees and grants finance the construction and improvement of rural electric infrastructure. In an effort by the RUS Electric Program to administer its program in an efficient and effective manner while improving its customer service and experience, and in response to requests from the RUS Electric Program borrowers, the Electric Program undertook a systematic review of regulations and procedures in place to administer its program. On July 9, 2019, Streamlining Electric Program Procedures (84 FR 32607) was published in the **Federal Register**. That regulation streamlined some pre- and post-loan procedures to be made more efficient and to reduce regulatory burden on Electric Program borrowers while still ensuring RUS loans remained adequately secured and ensuring that loan funds would be repaid in the time agreed upon.

This rulemaking is part of the Electric Program's continuing effort to improve customer service for its borrowers and to create a more efficient work process for its staff. This rulemaking will continue to streamline Electric Program procedures and revise regulations; including, removing unnecessary and outdated regulations and simplifying other policies and procedures that impose burdensome requirements on borrowers and applicants.

To implement this change, the Agency will publish this as a final rule. The Administrative Procedure Act exempts from prior notice rules, any actions, ''relating to agency management or personnel or to public property, loans, grants, benefits, or contracts'' (5 U.S.C. 553(b)(A)).

II. Summary of Changes to Rule

(a) Changes to 7 CFR part 1710 ''General and Pre-Loan Policies and Procedures Common to Electric Loans and Guarantees'' include:

(1) Section 1710.109(c)(1) was updated to remove outdated language and to increase the general fund reimbursement period from 24 to 48 months. This will provide borrowers with more flexibility for when they can submit a loan application. It also parallels with the construction workplan period which is typically 48 months.

(2) Section 1710.251 was updated to make conforming changes from prior rulemakings. Paragraph (c)(7) was changed to ''Outdoor Lights'' for more flexibility and paragraph (c)(13) was added to provide borrowers with more clarification on eligible items approved for RUS financing.

(3) Section 1710.252(b) was revised to change the coverage period of construction workplans to typically 4 years. This is a conforming change from a prior rulemaking that streamlined when construction workplans must be approved.

(4) Section 1710.501(a)(3) was updated to clarify that the RUS Form 740c will be used to justify the loan amount and not be an exclusive list of projects which could be financed. This change will provide greater financing flexibility to the borrowers.

(b) Changes to 7 CFR part 1714—''Pre-Loan Policies and Procedures for Insured Electric Loans'' include removing outdated language and updating information on the fund advance period. The updated language will clarify the loan fund advance period to conform to the requirements of the Antideficiency Act, 31 U.S.C. 1341.

(c) Changes to 7 CFR part 1717—''Post-Loan Policies and Procedures Common to Insured and Guaranteed Electric Loans include:

(1) Section 1717.154(c) was amended to increase the general funds reimbursement period to 48 months. This is a conforming change to go with the modification made to § 1710.109(c)(1).

(2) Section 1717.604(b) was revised to removed outdated language that references the requirement that long-

range engineering plans must be approved by RUS. This is a conforming change to a prior rulemaking.

(3) Section 1717.608(b) was amended to change the current approval requirement to a notification and to increase the threshold for the notification. This change will reduce the amount of oversight for the borrower. Paragraph (c) was amended to change the RUS approval of Power Supply Arrangements and any amendments to a term of 5 years. This will decrease the wait time for borrowers. Both of these changes will allow the Agency to focus resources on contracts with potentially higher risks.

(4) Section 1717.616 introductory text was revised to apply to all borrowers and different coverage ratios will be reviewed on a case by case basis. Paragraph (b) was revised to remove the specific ratios with a cross reference to § 1710.114(b) and ''other financial requirements as established by their Mortgages, Loan Contracts and/or other Security Agreements'' was added. These changes provide the borrowers with more flexibility on ratios they are required to meet to sell property.

(5) Section 1717.854(c)(2) was amended to reduce the equity requirement related to RUS advance approval for lien sharing from 27 to 20 percent. This will reduce the number of borrowers that need to obtain prior approval before borrowing funds from an outside lender.

(d) Changes to 7 CFR part 1718—''Loan Security Documents for Electric Borrowers'' include removing appendix A to subpart B and appendix A to subpart C. These were removed because copies of the model mortgage and loan contract are available upon request as noted in §§ 1718.54 and 1718.104. Also, in § 1718.54, the reference to Administrative Services Division was removed for consistency.

(e) Changes to 7 CFR part 1721—''Post-Loan Policies and Procedures for Insured Electric Loans'' include revising § 1721.1(a) to identify those projects for which loan funds may be advanced and remove the requirement to amend an approved loan. This change provides greater financing flexibility for borrowers.

(f) Changes to 7 CFR part 1726—''Electric System Construction Policies and Procedures'' include:

(1) Section 1726.35 was revised to remove outdated references, allow a borrower to submit a certification statement in lieu of three copies of each contract (conforming change to prior rulemaking) and to provide for electronic submission of documents.

(2) Sections 1726.51(b) and 1726.77(b) were revised to increase the contract procurement limits and to allow for some Cost-Plus/Hourly contracts. These changes will provide greater flexibility to the borrowers related to contracting as well as reduce the number of requests submitted to the Agency for review and action.

(3) Section 1726.77(c) was revised to increase the limits for requiring contract approval and to set the contract approval threshold to be the same for all borrowers. This change simplifies the program regulation and potentially minimizes misinterpretation.

(4) Section 1726.150(b) was revised to increase contract procurement limits for headquarters buildings. This change is expected to create flexibility for the borrower.

(5) Section 1726.176 introductory text was revised to add Automated Meter Reading/Automated Metering Infrastructure to the list of items covered in the regulation. Paragraph (b)(3) was revised to set contract approval thresholds to be the same for all borrowers to simplify the program regulation and potentially minimize misinterpretation.

(6) Section 1726.403(c)(2)(ii) was revised to provide that a borrower may now submit a certification statement in lieu of closeout documents. It was also modified to remove the instruction that the closeout documents are to be submitted through the General Field Representative. These changes are intended to create process efficiency for the borrower.

(g) Changes to 7 CFR part 1730—''Electric System Operations and Maintenance'' include removing appendix A to subpart B and revising § 1730.23 to read ''The RUS Form 300 is available from RUS and shall be used when required by this part.'' RUS seeks to remove appendix A to subpart B to adapt program rules so that the program can be delivered effectively, efficiently and consistent with the current industry developments and technology changes.

(h) Changes to 7 CFR part 1767—''Accounting Requirements for RUS Electric Borrowers'' include modifications to § 1767.41 Number 119 ''Special Equipment'' to provide clarification and additional guidance related to the treatment of Special Equipment.

III. Executive Orders and Acts

Executive Order 12866

This final rule has been determined to be non-significant for purposes of Executive Order (E.O.) 12866 and therefore has not been reviewed by the Office of Management and Budget (OMB).

Congressional Review Act

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

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) number assigned to the Rural Electrification Loans and Loan Guarantees Program is 10.850. The Catalog is available on the internet at *https://beta.sam.gov/*. The Government Publishing Office (GPO) prints and sells the CFDA to interested buyers. For information about purchasing the Catalog of Federal Domestic Assistance from GPO, call the Superintendent of Documents at (202) 512–1800 or toll free at (866) 512–1800, or access GPO's online bookstore at *https://bookstore.gpo.gov*.

Executive Order 12372, Intergovernmental Review of Federal Programs

This rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require a consultation with State and local officials. See the final rule related notice entitled, ''Department Programs and Activities Excluded from Executive Order 12372'' (50 FR 47034) advising that RUS loans and loan guarantees were not covered by Executive Order 12372.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The Agency has determined that this final rule does not have a substantial direct effect on one or more Indian tribe(s) or on either the relationship or the distribution of powers and responsibilities between the Federal Government and Indian tribes. Thus, this final rule is not subject to the requirements of Executive Order 13175. Consequently, the Agency will not conduct tribal consultation sessions. If a Tribe determines that this rule has implications of which RUS is not aware and would like to request government-to-government consultation on this rule, please contact USDA Rural Development's Native American Coordinator at (720) 544–2911 or *AIAN@usda.gov*.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil

Justice Reform. In accordance with this final rule: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) No retroactive effect will be given to this rule; and (3) Administrative proceedings of the National Appeals Division (7 CFR part 11) must be exhausted before bringing suit in court challenging action taken under this rule.

National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, Public Law 91–190, this final rule has been reviewed in accordance with 7 CFR part 1970 (''Environmental Policies and Procedures''). The Agency has determined that (i) this action meets the criteria established in 7 CFR 1970.53(f); (ii) no extraordinary circumstances exist; and (iii) the action is not ''connected'' to other actions with potentially significant impacts, is not considered a ''cumulative action'' and is not precluded by 40 CFR 1506.1. Therefore, the Agency has determined that the action does not have a significant effect on the human environment, and therefore neither an Environmental Assessment nor an Environmental Impact Statement is required.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, RUS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires RUS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This final rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this final rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute. This final rule; however, is not subject to the APA under 5 U.S.C. 553(a)(2) and 5 U.S.C. 553(b)(3)(A) nor any other statute.

Executive Order 13132, Federalism

It has been determined, under E.O. 13132, Federalism, that the policies contained in this final rule do not have any substantial direct effect on states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Nor does this final rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with the states is not required.

E-Government Act Compliance

The Agency is committed to complying with the E-Government Act of 2002, Public Law 107–347, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible and 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.

Information Collection and Recordkeeping Requirements

The information collection and record-keeping requirements contained in this rule are approved by the Office of Management and Budget (OMB) under OMB Control Numbers 0572–0003, 0572–0025, 0572–0032, 0572–0100, 0572–0114, 0572–0107, and 0572–0123.

Civil Rights Impact Analysis

Rural Development, a mission area for which RUS is an agency, has reviewed this rule in accordance with USDA Regulation 4300–4, Civil Rights Impact Analysis,'' to identify any major civil rights impacts the rule might have on program participants on the basis of age, race, color, national origin, sex, or disability. After review and analysis of the rule and available data, it has been determined that based on the analysis of the program purpose, application submission and eligibility criteria, issuance of this final rule is not likely to negatively impact very low, low and moderate-income populations, minority populations, women, Indian tribes or persons with disability, by virtue of their race, color, national origin, sex, age, disability, or marital or familial status. No major civil rights impact is likely to result from this rule.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) Fax: (202) 690–7442; or (3) Email: *OAC@usda.gov* USDA is an equal opportunity provider, employer, and lender.

List of Subjects

7 CFR Part 1710

Electric power, Grant programs—energy, Loan programs—energy, Reporting and recordkeeping requirements, Rural areas.

7 CFR Part 1714

Electric power, Loan programs—energy, Rural areas.

7 CFR Part 1717

Administrative practice and procedure, Electric power, Electric power rates, Electric utilities, Intergovernmental relations, Investments, Loan programs—energy, Reporting and recordkeeping requirements, Rural areas.

7 CFR Part 1718

Administrative practice and procedure, Electric power, Electric utilities, Loan programs—energy, Reporting and recordkeeping, Rural areas.

7 CFR Part 1721

Electric power, Loan programs—energy, Rural areas.

7 CFR Parts 1726 and 1730

Electric power, Loan programs—energy, Reporting and recordkeeping requirements, Rural areas.

7 CFR Part 1767

Electric power, Loan programs—energy, Rural areas, Uniform System of Accounts.

For the reasons set forth in the preamble, RUS amends 7 CFR parts 1710, 1714, 1717, 1718, 1721, 1726, 1730, and 1767 as follows:

PART 1710—GENERAL AND PRE-LOAN POLICIES AND PROCEDURES COMMON TO ELECTRIC LOANS AND GUARANTEES

■ 1. The authority citation for part 1710 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

Subpart C—Loan Purposes and Basic Policies

■ 2. Amend § 1710.109 by revising paragraph (c) to read as follows:

§ 1710.109 Reimbursement of general funds and interim financing.

* * * * *

(c) The period immediately preceding the current loan period for which reimbursement and replacement of interim financing is authorized under paragraph (b) of this section is 48 months. Policies for reimbursement of general funds and interim financing following certain mergers, consolidations, and transfers of systems substantially in their entirety are set forth in 7 CFR 1717.154.

* * * * *

Subpart F—Construction Work Plans and Related Studies

■ 3. Amend § 1710.251 by:

■ a. Revising the first sentence of paragraph (b);

■ b. Revising paragraph (c)(7);

■ c. Revising the last sentence of paragraph (c)(11);

■ d. Revising paragraph (c)(12); and

■ e. Adding paragraph (c)(13).

The revisions and addition read as follows:

§ 1710.251 Construction work plans—distribution borrowers.

* * * * *

(b) A distribution borrower's CWP shall typically cover a construction period of 4 years and includes all facilities to be constructed which are eligible for RUS financing, whether or not RUS financial assistance will be sought or be available for certain facilities. * * *

(c) * * *

(7) Outdoor lights;

* * * * *

(11) * * * To be eligible for financing, such equipment must be owned by the borrower, although it may be located inside or outside a consumer's premises;

(12) The cost of engineering, architectural, environmental, and other studies and plans needed to support the construction of facilities, when such cost is capitalized as part of the cost of the facilities; and

(13) Other items that are specifically determined by RUS as being eligible for financing prior to inclusion in the CWP.

■ 4. Amend § 1710.252(b) by revising the first sentence to read as follows:

§ 1710.252 Construction work plans—power supply borrowers.

* * * * *

(b) Typically a power supply borrower's CWP shall cover a period of 4 years. * * *

* * * * *

Subpart I—Application Requirements and Procedures for Loans

■ 5. Amend § 1710.501 by revising paragraph (a)(3) introductory text to read as follows:

§ 1710.501 Loan application documents.

* * * * *

(a) * * *

(3) *RUS Form 740c, Cost Estimates and Loan Budget for Electric Borrowers.* This form together with its attachments lists the construction, equipment, facilities, and other cost estimates from the construction work plan or engineering and cost studies. The projects and related costs, included on this form, shall be used to justify the loan amount and are not meant to be an exclusive list of those projects that could receive funds under this loan. In addition, to be included on this form, the project must have received written documentation of RUS concluding its environmental review. The advance of loan funds for projects shall be governed by 7 CFR part 1721. The date on page one (1) of the RUS Form 740c is the beginning date of the loan period. RUS Form 740c also includes the following information, exhibits, and attachments:

* * * * *

PART 1714—PRE-LOAN POLICIES AND PROCEDURES FOR INSURED ELECTRIC LOANS

■ 6. The authority citation for part 1714 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.;* 1921 *et seq.;* and 6941 *et seq.*

Subpart B—Terms of Insured Loans

■ 7. Amend § 1714.56 by revising paragraphs (a) and (b) to read as follows:

§ 1714.56 Fund advance period.

(a) The fund advance period begins on the date of the loan note and will last no longer than five years after September 30 of the fifth year after the fiscal year of obligation. The fiscal year of obligation is identified in loan documentation associated with each loan. The Administrator may extend the fund advance period on any loan if the borrower meets the requirements of paragraph (b) of this section. However, under no circumstances shall the RUS ever make or approve an advance, regardless of the last day for an advance on the loan note or any extension by the Administrator, later than September 30 of the fifth year after the fiscal year of obligation if such date would result in the RUS obligating or permitting advance of funds contrary to the Antideficiency Act, 31 U.S.C. 1341.

(b) The Administrator may agree to an extension of the fund advance period for loans if the borrower demonstrates, to the satisfaction of the Administrator, that the loan funds continue to be needed for approved loan purposes (*i.e.,* facilities included in a RUS approved construction work plan). Policies for extension of the fund advance period following certain mergers, consolidations, and transfers of systems substantially in their entirety are set forth in 7 CFR 1717.156.

* * * * *

PART 1717—POST-LOAN POLICIES AND PROCEDURES COMMON TO INSURED AND GUARANTEED ELECTRIC LOANS

■ 8. The authority citation for part 1717 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

Subpart D—Mergers and Consolidations of Electric Borrowers

§ 1717.154 [Amended]

■ 9. Amend § 1717.154(c)(1) by removing the number ''24'' in the second sentence and adding ''48'' in its place.

Subpart M—Operational Controls

■ 10. Amend § 1717.604 by revising paragraphs (b) and (c) to read as follows:

§ 1717.604 Long-range engineering plans and construction work plans.

* * * * *

(b) Applications for financing from RUS must be supported by a CWP approved by RUS.

(c) RUS approval is not required for CWPs if the borrower does not intend to seek RUS financing for any of the facilities, equipment, or other purposes included in those plans. However, if requested by RUS, a borrower must provide an informational copy of such plans to RUS.

■ 11. Amend § 1717.608 by revising paragraphs (b) and (c)(1) to read as follows:

§ 1717.608 RUS approval of contracts.

* * * * *

(b) *Large retail power contracts.* RUS is required to be notified of contracts to sell electric power to retail customers if the contract is for longer than 5 years and the kWh sales or kW demand for any year covered by the contract exceeds 25 percent of the borrower's total kWh sales or maximum kW demand for the year immediately preceding execution of the contract. The requirement in this paragraph (b) applies regardless of the source of funding of any plant extensions, additions or improvements that may be involved in connection with the contract.

(c) * * *

(1) Power supply contracts (including but not limited to economy energy sales and emergency power and energy sales), interconnection agreements, interchange agreements, wheeling agreements, pooling agreements, and any other similar power supply arrangements subject to approval by RUS are deemed approved if they have a term of 5 years or less. Amendments to said power supply arrangements are also deemed approved provided that the amendment does not extend the term of the arrangement for more than 5 years beyond the date of the amendment.

* * * * *

■ 12. Amend § 1717.616 by revising the introductory text and paragraph (b) to read as follows:

§ 1717.616 Sale, lease, or transfer of capital assets.

A borrower may, without the prior approval of RUS, sell, lease, or transfer any capital asset if the following conditions are met:

* * * * *

(b) In the most recent year for which data is available, the borrower has met its coverage ratios as set in 7 CFR part 1710.114(b) or other financial requirements as established by their Mortgages, Loan Contracts, and/or other Security Agreements;

* * * * *

Subpart R—Lien Accommodations and Subordinations for 100 Percent Private Financing

§ 1717.854 [Amended]

■ 13. Amend § 1717.854(c)(2) by removing the number ''27'' and adding ''20'' in its place.

PART 1718—LOAN SECURITY DOCUMENTS FOR ELECTRIC BORROWERS

■ 14. The authority citation for part 1718 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

Subpart B—Mortgage for Distribution Borrowers

§ 1718.54 [Amended]

■ 15. Amend § 1718.54 introductory text by removing ''Administrative Services Division.''

Appendix A to Subpart B [Removed]

■ 16. Remove appendix A to subpart B.

Subpart C—Loan Contracts With Distribution Borrowers

Appendix A to Subpart C [Removed]

■ 17. Remove appendix A to subpart C.

PART 1721—POST-LOAN POLICIES AND PROCEDURES FOR INSURED ELECTRIC LOANS

■ 18. The authority citation for part 1721 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.;* 1921 *et seq.;* and 6941 *et seq.*

Subpart A—Advance of Funds

■ 19. Amend § 1721.1 by revising paragraph (a) to read as follows:

§ 1721.1 Advances.

(a) *Purpose and amount.* With the exception of minor projects which are addressed in paragraph (b) of this section and generation projects which need to be included on a RUS Form 740c or an amendment to a RUS Form 740c, loan funds will be advanced for projects which are included in a RUS approved construction work plan (CWP), Energy Efficiency and Conservation Program work plan (EEWP), or approved amendment to either, have received written documentation of RUS concluding its environmental reviews and have complied with all Contracting and Bidding Procedures included in 7 CFR part 1726. Loan fund advances can be requested in an amount representing actual costs incurred.

* * * * *

PART 1726—ELECTRIC SYSTEM CONSTRUCTION POLICIES AND PROCEDURES

■ 20. The authority citation for part 1726 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

Subpart A—General

■ 21. Amend § 1726.35 by revising paragraphs (a), (c) introductory text, (c)(3), and (d) to read as follows:

§ 1726.35 Submission of documents to RUS.

(a) *Where to send documents.* Documents required to be submitted to RUS under this part are to be sent electronically to RUS, unless otherwise directed.

* * * * *

(c) *Contracts requiring RUS approval.* The borrower shall submit to RUS, one copy of each contract that is subject to RUS approval under subparts B through F of this part. Any contract submitted by the borrower contract must be accompanied by:

* * * * *

(3) One copy of an executed contractor's bond on RUS approved bond forms as required in the contract form and one copy of the bid bond or copy of the certified check.

* * * * *

(d) *Contract amendments requiring RUS approval.* The borrower must

submit to RUS, one copy of each contract amendment which is subject to RUS approval under § 1726.24(b). Each contract amendment submittal to RUS must be accompanied by a bond extension, where necessary.

* * * * *

Subpart B—Distribution Facilities

■ 22. Amend § 1726.51 by revising paragraph (b) to read as follows:

§ 1726.51 Distribution line construction.

* * * * *

(b) *Procurement procedures.* (1) It is the responsibility of each borrower to determine the procurement method that best meets its needs to award contracts in amounts of up to a cumulative total of $750,000 or three percent of NUP (not to exceed $6,000,000), whichever is greater, per calendar year of distribution line construction (including minor modifications or improvements), exclusive of the cost of owner furnished materials and equipment. Borrowers may award Cost-Plus/Hourly contracts as part of these borrower responsibility limits up to a cumulative total of $250,000 or one percent of NUP (not to exceed $2,000,000), whichever is greater, per calendar year of distribution line construction (including minor modifications or improvements), exclusive of the cost of owner furnished materials and equipment.

(2) The borrower shall use formal competitive bidding for all other distribution line contract construction unless the RUS specifically approves an alternative method. The dollar amounts of contracts bid using the formal competitive bidding procedure do not apply to the cumulative total stipulated in paragraph (b)(1) of this section.

(3) An amendment which increases the scope of the contract by adding a project is not considered competitively bid, therefore, the dollar amount of that amendment does apply to the cumulative total stipulated in paragraph (b)(1) of this section.

* * * * *

Subpart C—Substation and Transmission Facilities

■ 23. Amend § 1726.77 by revising paragraphs (b) and (c) to read as follows:

§ 1726.77 Substation and transmission line construction.

* * * * *

(b) *Procurement procedures.* (1) It is the responsibility of each borrower to determine the procurement method that best meets its needs to award contracts in amounts of up to a cumulative total of $750,000 or three percent of NUP (not to exceed $6,000,000), whichever is greater, per calendar year of substation and transmission line construction (including minor modifications or improvements), exclusive of the cost of owner furnished materials and equipment. Borrowers may award Cost-Plus/Hourly contracts as part of these borrower responsibility limits up to a cumulative total of $250,000 or one percent of NUP (not to exceed $2,000,000), whichever is greater, per calendar year of substation and transmission line construction (including minor modifications or improvements), exclusive of the cost of owner furnished materials and equipment.

(2) The borrower shall use formal competitive bidding for all other contract construction unless RUS specifically approves an alternative method. The dollar amount of contracts bid using the formal competitive bidding procedure do not apply to the cumulative total stipulated in paragraph (b)(1) of this section.

(3) An amendment which increases the scope of the contract by adding a project is not considered competitively bid, therefore, the dollar amount of that amendment does apply to the cumulative total stipulated in paragraph (b)(1) of this section.

(c) *Contract approval.* Individual contracts in the amount of $750,000 or more or three percent of NUP (not to exceed $6,000,000), whichever is greater, exclusive of the cost of owner furnished materials and equipment, are subject to RUS approval.

Subpart E—Buildings

■ 24. Amend § 1726.150 by revising paragraph (b) to read as follows:

§ 1726.150 Headquarters buildings.

* * * * *

(b) *Procurement procedures.* A borrower may use Multiparty Lump Sum Quotations to award contracts in amounts of up to a cumulative total of $1,500,000 or three percent of NUP (not to exceed $10,000,000), whichever is greater, per calendar year of headquarters construction (including minor modifications or improvements). The borrower shall use formal competitive bidding for all other headquarters contract construction unless RUS specifically approves an alternative method.

* * * * *

Subpart F—General Plant

■ 25. Amend § 1726.176 by revising the introductory text and paragraph (b)(3) to read as follows:

§ 1726.176 Communications and control facilities.

This section covers the purchase of microwave, fiber, power line carrier, and other communications technologies or systems, including load control and supervisory control and data acquisition (SCADA) systems, automated meter reading/automated metering infrastructure (AMR/AMI), or other smart grid technologies. Mobile radio systems are covered as general plant materials in § 1726.175.

* * * * *

(b) * * *

(3) *Contract approval.* Individual contracts in amounts of $750,000 or more or one percent of NUP (not to exceed $5,000,000 for all borrowers), whichever is greater, exclusive of the cost of owner furnished materials and equipment, are subject to RUS approval.

Subpart J—Contract Closeout

■ 26. Amend § 1726.403 by revising paragraph (c)(2)(ii) introductory text to read as follows:

§ 1726.403 Project construction contract closeout.

* * * * *

(c) * * *

(2) * * *

(ii) For contracts subject to RUS approval, the borrower will submit either a certification or the following closeout documents for RUS approval:

* * * * *

PART 1730—ELECTRIC SYSTEM OPERATIONS AND MAINTENANCE

■ 27. The authority citation for part 1730 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

Subpart B—Operations and Maintenance Requirements

■ 28. Revise § 1730.23 to read as follows:

§ 1730.23 Review rating summary, RUS Form 300.

The RUS Form 300 is available from RUS and shall be used when required by this part.

Appendix A to Subpart B [Removed]

■ 29. Remove appendix A to subpart B.

PART 1767—ACCOUNTING REQUIREMENTS FOR RUS ELECTRIC BORROWERS

■ 30. The authority citation for part 1767 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* 6941 *et seq.*

Subpart B—Uniform System of Accounts

■ 31. Amend § 1767.41 by revising entry 119 to read as follows:

§ 1767.41 Accounting methods and procedures required of all RUS borrowers.

* * * * *

119 Special Equipment

Special Equipment items are classified separately from work order items. The USoA provides accounting that differs from that used for other types of materials. The cost of new, special equipment items shall be capitalized at the time of purchase; it shall not be charged to Account 154 as is the case with other materials. The first installation cost, as well as all incidental costs necessary to prepare the equipment for use, shall be capitalized with the material upon purchase. All subsequent costs of removing, resetting, changing, renewing oil, and repairing constitute operations and maintenance expenses. The capitalized cost of special equipment items, including the first installation, shall be removed from the electric plant accounts only when the items are abandoned or retired from the system. Borrowers may request a waiver from the special equipment accounting requirements as described later in this section.

Special Equipment Items include the following:

1. Reclosers and Sectionalizers recorded in Account 365, Conductor and Devices
2. Transformers, Capacitors and Voltage Regulators recorded in Account 368, Line Transformers
3. Meters, Meter Sockets, current and potential transformers, and other metering equipment recorded in Account 379, Meters
4. Load Control Devices recorded in Account 371, Installations on Customers' Premises (See Interpretation No. 118)

Note: Equipment installed in a substation is not considered special equipment.

Special equipment items which are classified as nonusable shall be segregated in the warehouse and retired from service. The Summary of Special Equipment Costs shall be retitled Summary of Special Equipment Costs Retired and used for this purpose. A journal entry reflecting this information shall be prepared and posted to the books. Since loan funds for special equipment, including first installation costs, are approved for advance by the Rural Development upon receipt of the borrower's written estimate of funds required, and not on the basis of an Inventory of Work Orders, it is improper to take a credit for any salvage involved in the retirement of special equipment on the Inventory of Work Orders.

Electric borrowers that wish to receive a waiver from the special equipment accounting requirements should submit a letter request to Rural Development. In order to expedite these requests the letter to Rural Development should state that the borrower will adhere to the following requirements to account for special equipment using the work order procedure rather than the special equipment accounting procedures prescribed by Rural Development:

1. New purchases of special equipment items are to be charged to Account 154, Materials and Supplies, upon purchase.

2. Labor, material and overhead costs associated with the initial installation and all subsequent installations of special equipment are recorded on construction work orders and charged to the appropriate plant accounts upon closeout of the construction work order.

3. Labor and overhead costs associated with the removal of special equipment items, whether the items removed are placed in inventory or permanently retired and disposed of, are recorded on retirement work orders and charged or credited to the depreciation reserve account upon closeout of the retirement work order.

4. The special equipment items retired and salvaged for reuse are returned to the materials and supplies account at the average material cost in the materials and supplies account and credited to the depreciation reserve upon closeout of the retirement work order.

In addition to recognition of the requirements noted above, the borrower should indicate how it plans to account for the items of special equipment that have been charged to the plant accounts but not installed (in inventory). Two acceptable methods to account for this equipment are: (1) Leave the equipment in the plant accounts until the inventory is depleted and charge only new purchases to materials and supplies, or (2) credit the plant accounts for the installed cost of the equipment in inventory, charge the equipment cost to materials and supplies, and charge the installation cost to the appropriate operations expense account. Also, under the second method, the borrower must submit a ''negative'' special equipment summary to Rural Development to return to the balance in reserve for the current loan the installed cost of special equipment in inventory on the date of transition.

* * * * *

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2021–14358 Filed 7–8–21; 8:45 am]

BILLING CODE 3410–15–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part Chapter XII

[No. 2021–N–7]

Policy Statement on Fair Lending

AGENCY: Federal Housing Finance Agency.

ACTION: Notification of approval and adoption of policy statement; request for comment.

SUMMARY: The Federal Housing Finance Agency (FHFA or agency) is issuing a policy statement on Fair Lending (Policy Statement) to communicate the agency's general position on monitoring and information gathering, supervisory examinations, and administrative enforcement related to the Equal Credit Opportunity Act, the Fair Housing Act, and the Federal Housing Enterprises Financial Safety and Soundness Act, and is soliciting comments on its application.

DATES: The Policy Statement becomes effective on July 9, 2021. Comments must be received on or before September 7, 2021.

FOR FURTHER INFORMATION CONTACT: Annalyce Shufelt, Senior Attorney Advisor (Fair Lending), Office of Fair Lending Oversight, (202) 649–3416, *Annalyce.Shufelt@fhfa.gov,* Federal Housing Finance Agency, Constitution Center, 400 7th Street SW, Washington, DC 20219; or Ming-Yuen Meyer-Fong, Associate General Counsel, Office of General Counsel, (202) 649–3078 (not toll-free numbers), *Ming-Yuen.Meyer-Fong@fhfa.gov.* The Telecommunications Device for the Deaf is (800) 877–8339.

ADDRESSES: FHFA welcomes comments about application of the principles set out in the policy statement to specific policies and practices. You may submit your comments to FHFA, identified by ''Policy Statement; Comment Request: (2021–N–7)'', by any one of the following methods:

- *Agency website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If

you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by FHFA. Include the following information in the subject line of your submission: ''Policy Statement; Comment Request: (2021–N–7).''

- *Hand Delivered/Courier:* The hand delivery address is: Clinton Jones, General Counsel, Attention: ''Policy Statement; Comment Request: (2021–N–7)'', Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW, Washington, DC 20219. Deliver the package at the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Clinton Jones, General Counsel, Attention: ''Policy Statement; Comment Request: (2021–N–7)'', Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW, Washington, DC 20219. Please note that all mail sent to FHFA via U.S. Mail is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, email address, and telephone number, on the FHFA website at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public through the electronic comment docket also located on the FHFA website.

SUPPLEMENTARY INFORMATION:

I. Purpose

FHFA is the primary regulator for Fannie Mae and Freddie Mac (the Enterprises) and the Federal Home Loan Banks (the Banks) (collectively, the regulated entities). FHFA is issuing this Policy Statement to communicate FHFA's general position on monitoring and information gathering, supervisory examinations, and administrative enforcement related to the Equal Credit Opportunity Act (ECOA), 15 U.S.C. 1691 *et seq.,* the Fair Housing Act, 42 U.S.C. 3601 *et seq.,* and section 4545 of the Federal Housing Enterprises Financial Safety and Soundness Act (Safety and Soundness Act), 12 U.S.C. 4501 *et seq.* (collectively, with implementing regulations and other sources, ''fair lending laws''). This Policy Statement is intended to be consistent with those statutes and their implementing regulations and to provide guidance to FHFA's regulated entities seeking to comply with them. It describes sources of statutory authority for actions that may be taken by FHFA and it articulates FHFA's policies for supervisory oversight and enforcement of fair lending matters. FHFA is also issuing this Policy Statement to provide a foundation for possible future interpretations and rulemakings by the agency for its regulated entities.[1]

II. Policy Statement

Fair Lending Policy Statement

FHFA is committed to ensuring that its regulated entities operate consistently with the public interest and with sufficient overall risk management by providing fair, equitable, and nondiscriminatory access to credit and housing. Fair lending is central to the principles under which the U.S. housing finance system operates and is a requirement of law. FHFA will never tolerate illegal discrimination by the regulated entities. FHFA will engage in comprehensive fair lending oversight of its regulated entities and adopts the following high-level policies to guide its fair lending monitoring, supervision, and enforcement. FHFA is committed to interagency engagement, coordination, and collaboration in fair lending.

Legal Overview

While many Federal statutes seek to promote fair lending, FHFA's policy statement focuses on ECOA, the Fair Housing Act, and the fair lending provisions of the Safety and Soundness Act as they apply to the regulated entities' activities. This policy statement does not create or confer any substantive or procedural rights which could be enforceable in any administrative or civil proceeding.

The Consumer Financial Protection Bureau's (CFPB) Regulation B, 12 CFR part 1002, along with Official Interpretations in Supplement I to 12 CFR part 1002, implements ECOA.[2] The U.S. Department of Housing and Urban Development's (HUD) regulations at 24 CFR part 100 implement the Fair Housing Act. Together, these statutes and regulations prohibit discrimination on the basis of race or color, religion, national origin, sex, marital status, age (provided the applicant has the capacity to contract), receipt of income derived from any public assistance program, exercise, in good faith, of any right under the Consumer Credit Protection Act, familial status (defined by 42 U.S.C. 3602(k) of the Fair Housing Act as children under the age of 18 living with a parent or legal custodian, pregnant women, and people securing custody of children under 18), and disability.[3]

The Enterprises are also subject to section 4545 of the Safety and Soundness Act, which requires HUD, by regulation, to prohibit the Enterprises from discriminating in the purchase of mortgages on the bases of race, color, religion, sex, disability, familial status, age, or national origin, including any consideration of the age or location of the dwelling or the age of the neighborhood or census tract where the dwelling is located in a manner that has a discriminatory effect.[4]

FHFA also recognizes that there are a number of applicable and relevant sources of fair lending law and guidance, including judicial decisions, administrative interpretations and guidance, and administrative actions.

Fair Lending Oversight Considerations

FHFA has broad statutory authority to supervise the regulated entities, including authority to monitor and gather information, conduct supervisory examinations, and enforce compliance with law where appropriate. FHFA monitors regulated entities for fair lending risk, conducts supervisory examinations, and, when necessary,

[1] As a historical note, in 1994, a number of Federal agencies published a Policy Statement on Discrimination in Lending (1994 Statement) which, in part, described how Federal agencies use their authorities to oversee fair lending compliance. *See* 59 FR 18266 (April 15, 1994). FHFA did not exist at the time and was not a signatory. In 2008, Congress abolished the former Office of Federal Housing Enterprise Oversight and the Federal Housing Finance Board, which had been parties to the 1994 Statement. In their place, Congress established FHFA with authorities that, in contrast to its predecessor agencies, include overseeing Enterprise and Bank compliance with applicable law. 12 U.S.C. 4511(b) (FHFA ''shall have general regulatory authority over each regulated entity . . . and shall exercise such general regulatory authority . . . to ensure that the purposes of this Act, the authorizing statutes, and any other applicable law are carried out''). Given the importance of fair lending compliance, FHFA is publishing this FHFA Policy Statement on Fair Lending to implement its authorities and articulate agency activities in relevant areas including monitoring, examination, enforcement, and coordination to oversee regulated entity fair lending compliance.

[2] The Federal Reserve Board of Governors also implements ECOA through a regulation covering auto dealers.

[3] The Fair Housing Act uses the term ''handicap'' instead of ''disability.'' This document uses the term ''disability,'' which is more generally accepted. *See* Joint Statement of the Department of Housing and Urban Development and the Department of Justice on Accessibility (Design and Construction) Requirements for Covered Multifamily Dwellings under the Fair Housing Act, April 30, 2013, *available at https://www.hud.gov/sites/documents/JOINTSTATEMENT.PDF* (*citing Bragdon* v. *Abbott,* 524 U.S. 624, 631 (1998), to say that both terms have the same legal meaning).

[4] 12 U.S.C. 4545.

takes enforcement action to ensure compliance with fair lending laws.

Monitoring and Information Gathering

FHFA regularly monitors the fair lending risk presented by Enterprise and Bank activities and may request data and information in its role as supervisor and regulator to ensure effective, ongoing oversight. FHFA reviews the regulated entities' internal fair lending data monitoring, risk assessments, policies and procedures, internal control systems, and other information to appropriately scope monitoring and examinations commensurate with fair lending risk. Fair lending monitoring information may be collected pursuant to FHFA's supervisory and regulatory authority, including 12 U.S.C. 4514(a) which authorizes FHFA to order regulated entities to submit both regular and special reports. FHFA may require regulated entities to submit ''regular reports . . . on the condition (including financial condition), management, activities, or operations of the regulated entity, as the Director considers appropriate.'' [5] Fair lending monitoring information includes, but is not limited to: Data and other information necessary to monitor and evaluate the policies, programs, and activities of the regulated entities; information about changes in policies, programs, and activities; information about the regulated entities' fair lending testing and other compliance activities; and the regulated entities' self-evaluations of fair lending risk and the compliance of their policies, programs, and activities with respect to fair lending laws.

Supervisory Examinations

FHFA has broad authority to supervise the Enterprises and the Banks for compliance with fair lending standards. The regulated entities are subject to FHFA's overarching ''supervision and regulation.'' [6] FHFA may conduct examinations of the regulated entities whenever FHFA determines that an examination is necessary or appropriate.[7] FHFA examiners have examination authority equivalent to other Federal prudential regulators.[8] FHFA also has a duty to ensure that the regulated entities are operating consistently with the public interest.[9]

FHFA conducts risk-based fair lending examinations of the regulated entities. FHFA's fair lending oversight program is committed to effective, appropriately tailored supervisory measures to ensure that the regulated entities adhere to applicable fair lending compliance standards. The Enterprises and the Banks each engage in activities that present differing levels and kinds of fair lending risk. FHFA carefully weighs the totality of available information, including monitoring information, market intelligence, and relevant data, when considering how best to employ supervisory resources.

Enforcement

FHFA may use its administrative enforcement authority to address violations of ECOA and the Fair Housing Act by the regulated entities. That a regulated entity is in conservatorship does not preclude other enforcement actions; however, the conservator's broad statutory powers may provide FHFA with more efficient means to address problems than traditional enforcement tools. FHFA as conservator may take immediate action, consistent with applicable law, to direct or restrict the activities at the regulated entity, including the activities of the board of directors and executive management.

FHFA has broader enforcement authority than its predecessor agencies FHFB and OFHEO, including for fair lending violations. The Housing and Economic Recovery Act (HERA) [10] granted FHFA the authority to use cease and desist orders to enforce violations of all applicable laws, including ECOA and the Fair Housing Act.[11] FHFA may also use civil money penalties as a tool to ensure fair lending compliance, where the statutory bases for such penalties are present.[12]

Prior to HERA, OFHEO's fair lending enforcement authority over the Enterprises was limited to the Safety and Soundness Act fair housing provision and HUD's implementing regulation.[13] HUD's implementing regulation anticipates HUD referring violations and potential violations of that provision by an Enterprise to FHFA for enforcement.[14] FHFA will support enforcement of HUD's regulation implementing the Safety and Soundness Act's fair housing provision. FHFA will conduct a full review of HUD's referral of a violation or potential violation and all evidence submitted as part of the referral and resolve the matter appropriately and in accordance with FHFA's enforcement policy and in consultation with HUD. In addition, FHFA will continue to facilitate HUD's periodic fair lending reviews of the Enterprises. FHFA may also independently pursue administrative enforcement actions for any violations of section 4545 of the Safety and Soundness Act.

FHFA's enforcement policy applies when taking any enforcement action against regulated entities for violations of law, including violations of fair lending law.[15] Pursuant to FHFA's enforcement policy, FHFA may engage in consent order negotiations with regulated entities to resolve violations of fair lending laws.[16] FHFA is not required by statute to refer potential fair lending violations to the Attorney General when the agency has a reason to believe that a regulated entity has engaged in a pattern or practice of discouraging or denying applications for

[5] 12 U.S.C. 4514(a).

[6] 12 U.S.C. 4511(b)(1) (''Each regulated entity shall, to the extent provided in this chapter, be subject to the supervision and regulation of the Agency''); 12 U.S.C. 4511(b)(2) (''The Director shall have general regulatory authority over each regulated entity and the Office of Finance, and shall exercise such general regulatory authority, including such duties and authorities set forth under section 4513 of this title, to ensure that the purposes of this Act, the authorizing statutes, and any other applicable law are carried out.'').

[7] 12 U.S.C. 4517(b).

[8] 12 U.S.C. 4517(e). The statute particularly references the authority of examiners employed by the Federal Reserve banks.

[9] 12 U.S.C. 4513(a)(1)(B)(v).

[10] The Housing and Economic Recovery Act of 2008 (HERA), Public Law 110–289 (July 30, 2008), *available at https://www.govinfo.gov/content/pkg/PLAW-110publ289/pdf/PLAW-110publ289.pdf.*

[11] Public Law 110–289, sec. 1101 (amended the former OFHEO authorities to provide the new FHFA general supervisory and regulatory authority requiring regulated entity compliance with the Safety and Soundness Act, the regulated entities statutory charters, and ''any other applicable law''); sec. 1151 (amended cease and desist authorities to include violations of law generally); *codified at* 12 U.S.C. 4511 and 4631.

[12] 12 U.S.C. 4636.

[13] *See* 24 CFR 81.47(a).

[14] 24 CFR 81.47(a). Under the Safety and Soundness Act, FHFA is empowered to initiate enforcement actions for Enterprise violations of 12 U.S.C. 4545 and HUD's implementing regulations. The process for referring ''violations or potential violations'' to FHFA under 24 CFR 81.47(a) is distinct from the process under 24 CFR 81.47(b), in which HUD shall conduct an investigation of the Fair Housing Act complaint, make a determination as to whether or not reasonable cause exists to believe discrimination occurred, and, if it does, proceed to enforcement under the Fair Housing Act.

[15] Federal Housing Finance Agency, Advisory Bulletin: FHFA Enforcement Policy, AB 2013–03 (issued May 31, 2013), *available at https://www.fhfa.gov/SupervisionRegulation/AdvisoryBulletins/AdvisoryBulletinDocuments/20130531_AB_2013-03_FHFA-Enforcement-Policy_508%20(2).pdf.*

[16] Federal Housing Finance Agency, Advisory Bulletin: FHFA Enforcement Policy, AB 2013–03 (issued May 31, 2013), *available at https://www.fhfa.gov/SupervisionRegulation/AdvisoryBulletins/AdvisoryBulletinDocuments/20130531_AB_2013-03_FHFA-Enforcement-Policy_508%20(2).pdf.* The Enforcement Policy further describes a number of informal and formal actions that FHFA may take, many of which may be used for enforcing compliance with fair lending laws.

credit.[17] Nevertheless, FHFA will consult with and refer matters to the Attorney General and coordinate with the Department of Justice on enforcement of fair lending matters as appropriate.

FHFA will consider whether the regulated entity has conducted any self-evaluations or undertaken any corrective actions when making supervisory and enforcement decisions. FHFA will view responsible business practices such as self-testing, implementation of management controls, and voluntary remedial action favorably when making fair lending supervisory and enforcement determinations. In particular, FHFA commits to taking into consideration an entity's cooperation and candor during examinations and monitoring. Regulated entities are not required to self-report potential violations of fair lending laws. However, self-reporting of violations of fair lending laws will be viewed favorably by FHFA as it exercises its discretion. FHFA also considers the number and duration of violations identified, the nature of the evidence of discrimination (*i.e.,* overt discrimination, disparate treatment, or disparate impact), the pervasiveness of the discrimination, the presence and effectiveness of any anti-discrimination policies, any history of discriminatory conduct, any corrective measures implemented or proposed by the regulated entity, and any other factors for determining the appropriateness of any potential action.

Consideration of Differences Between the Banks and the Enterprises

FHFA recognizes the important distinctions between the two types of regulated entities, the Enterprises and the Banks. In drafting this Policy Statement, FHFA has considered the differences between the Enterprises and the Banks with respect to the Banks' cooperative ownership structure, mission of providing liquidity to members, affordable housing and community development mission, capital structure, and joint and several liability, as well as other applicable differences.[18]

Sandra L. Thompson,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2021–14438 Filed 7–8–21; 8:45 am]

BILLING CODE 8070–01–P

[17] 15 U.S.C. 1691e(g).

[18] 12 U.S.C. 4513(f).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0542; Project Identifier MCAI–2021–00117–R; Amendment 39–21641; AD 2021–14–14]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model AW119 MKII helicopters. This AD was prompted by reports of detected smoke and burning smell during flight, caused by chafing of electrical wiring. This AD requires an inspection of the instrument panel electrical wiring, corrective actions if necessary, a modification of the wiring installation, and, for certain helicopters, an additional modification of the wiring installation, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective July 26, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 26, 2021.

The FAA must receive comments on this AD by August 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 the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0542.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0542; 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, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0040, dated January 27, 2021 (EASA AD 2021–0040) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Leonardo S.p.a. Model AW119 MKII helicopters.

This AD was prompted by reports of detected smoke and burning smell during flight, caused by chafing of electrical wiring. The FAA is issuing this AD to address detected smoke, burning smell during flight, and chafing of electrical wiring, which could lead to further occurrences of smoke in the cabin, or loss of function of avionics equipment, and possibly result in reduced control of the helicopter. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0040 specifies procedures for an inspection of the instrument panel electrical wiring for defects (including wire chafing; pinched, broken, or severely bent wires; deteriorated, cracked or missing wire shielding or insulation; and loose, corroded, or broken wire connectors), corrective actions (repair or replacement of the wiring and a pin to pin continuity

check on the repaired wiring) if necessary, a modification of the wiring installation, and, for certain helicopters, an additional modification of the wiring installation. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD after evaluating all pertinent information and determining that the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Requirements of This AD

This AD requires accomplishing the actions specified in EASA AD 2021–0040, described previously, as incorporated by reference, 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 initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2021–0040 is incorporated by reference in the FAA final rule. This AD will, therefore, require compliance with EASA AD 2021–0040 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 the EASA AD 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 the EASA AD. Service information specified in EASA AD 2021–0040 that is required for compliance with EASA AD 2021–0040 is available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0542.

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 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 of detected smoke, burning smell during flight, and chafing of electrical wiring, which could lead to further occurrences of smoke in the cabin, or loss of function of avionics equipment, and possibly result in reduced control of the helicopter. In addition, the compliance time for the inspection of the instrument panel electrical wiring is within 25 hours time-in-service or 3 months, whichever occurs first after the effective date of this AD, which is shorter than the time necessary for the public to comment and for publication of the final rule. Therefore, notice and opportunity for prior public comment are impracticable and contrary to 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.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0542; Project Identifier MCAI–2021–00117–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the AD, 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 AD 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 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 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 Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

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 10 helicopters 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 11 work-hours × $85 per hour = $935	$73	Up to $1,008	Up to $10,080.

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this AD would not have federalism implications under Executive Order 13132. This 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 regulation:

(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 adding the following new airworthiness directive:

2021–14–14 Leonardo S.p.a.: Amendment 39–21641; Docket No. FAA–2021–0542; Project Identifier MCAI–2021–00117–R.

(a) Effective Date

This airworthiness directive (AD) becomes effective July 26, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AW119 MKII helicopters, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2021–0040, dated January 27, 2021 (EASA AD 2021–0040).

(d) Subject

Joint Aircraft System Component (JASC) Code 3197, Instrument System Wiring.

(e) Unsafe Condition

This AD was prompted by reports of detected smoke and burning smell during flight, caused by chafing of electrical wiring. The FAA is issuing this AD to address detected smoke, burning smell during flight, and chafing of electrical wiring, which could lead to further occurrences of smoke in the cabin, or loss of function of avionics equipment, and possibly result in reduced control of the helicopter.

(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, EASA AD 2021–0040.

(h) Exceptions to EASA AD 2021–0040

(1) Where EASA AD 2021–0040 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2021–0040 does not apply to this AD.

(3) Where EASA AD 2021–0040 refers to flight hours (FH), this AD requires using hours time-in-service.

(4) Where paragraph (2) of EASA AD 2021–0040 specifies actions if ''any defect is found,'' for this AD a ''defect'' includes wire chafing; pinched, broken, or severely bent wires; deteriorated, cracked or missing wire shielding or insulation; and loose, corroded, or broken wire connectors.

(5) Where paragraph (1) of EASA AD 2021–0040 refers to ''the instructions of Part I of the SB,'' for this AD, use ''the instructions of Part I, paragraph 3. of the Accomplishment Instructions of the SB.''

(6) Where paragraph (2) of EASA AD 2021–0040 refers to ''the instructions of Part I of the SB,'' for this AD, use ''the instructions of Part I, paragraphs 4. and 5. of the Accomplishment Instructions of the SB.''

(7) Where paragraph (4) of EASA AD 2021–0040 refers to ''the instructions of Part II of the SB,'' for this AD, use ''the instructions of Part II, paragraph 1. of the Accomplishment Instructions of the SB.''

(8) Where the service information referenced in EASA AD 2021–0040 specifies to contact Leonardo if the cargo hoist indicator cable is damaged, this AD requires repair or replacement using a method approved by the Manager, International Validation Branch, FAA. The Manager's approval letter must specifically refer to this AD.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the helicopter can be modified (if the operator elects to do so), provided no passengers are onboard.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-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

For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@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 2021–0040, dated January 27, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0040, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +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 service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0542.

(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 *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 2, 2021.

Gaetano A. Sciortino,

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

[FR Doc. 2021–14690 Filed 7–7–21; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1180; Project Identifier MCAI–2020–00517–E; Amendment 39–21608; AD 2021–13–03]

RIN 2120–AA64

Airworthiness Directives; Safran Helicopter Engines, S.A. (Type Certificate Previously Held by Turbomeca, S.A.) Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Safran Helicopter Engines, S.A. (Safran Helicopter Engines) Arriel 2B, 2B1, 2C, 2C1, 2C2, 2S1 and 2S2 model turboshaft engines. This AD was prompted by reports of non-conforming fuel filter pre-blockage pressure switches. This AD requires repetitive visual inspections of the fuel filter by-pass indicator pop-up, a one-time operational test of the fuel filter pre-blockage pressure switch and, depending on the findings, replacement of the fuel filter pre-blockage pressure switch with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 13, 2021.

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

ADDRESSES: For service information identified in this final rule, contact Safran Helicopter Engines, S.A., Avenue du 1er Mai, Tarnos, France; phone: +33 (0) 5 59 74 45 11. 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–2020–1180.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1180; 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 Safran Helicopter Engines Arriel 2B, 2B1, 2C, 2C1, 2C2, 2S1 and 2S2 model turboshaft engines. The NPRM published in the **Federal Register** on February 22, 2021 (86 FR 10501). The NPRM was prompted by reports of non-conforming fuel filter pre-blockage pressure switches. In the NPRM, the FAA proposed to require repetitive visual inspections of the fuel filter by-pass indicator pop-up, a one-time operational test of the fuel filter pre-blockage pressure switch and, depending on the findings, replacement of the fuel filter pre-blockage pressure switch with a part eligible for installation. 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 2019–0180, dated July 25, 2019 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> Occurrences have been reported of non-conforming fuel filter pre-blockage pressure switches, manufactured before December 2016. The non-conformity of the fuel filter pre-blockage pressure switch can cause its non-activation in case of fuel system contamination, with consequent opening of the by-pass without indication in the cockpit.
>
> This condition, if not detected and corrected, and in case of fuel contamination, could lead to an uncommanded in-flight shut-down, possibly resulting in an emergency autorotation landing on a single engine helicopter, or to a double uncommanded in-flight shut-down on a twin engine helicopter.
>
> To address this potential unsafe condition, SAFRAN issued the MSB, providing inspection instructions.
>
> For the reasons described above, this [EASA AD] requires repetitive daily visual checks of the fuel filter by-pass indicator pop-up. This [EASA] AD also requires a one-

time operational check of the affected part and, depending on findings, replacement of that part, which constitutes terminating action for the repetitive daily checks as required by this [EASA] AD.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1180.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Task 73–23–01–750–801–A01—Pre-Blockage Pressure Switch of the Fuel Filter Tests (Electrical), dated November 30, 2012, from the Turbomeca Arriel 2 S1 Maintenance Manual. Task 73–23–01–750–801–A01 provides instructions for performing an operational test of the fuel filter pre-blockage pressure switch. 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 Safran Helicopter Engines Mandatory Service Bulletin (MSB) No. 292 73 2869, Version B, dated December 2018. The MSB describes procedures for identifying and securing pre-blockage pressure switches of fuel filter part number P/N 9 550 17 200 0, which are potentially non-conforming.

Justification for Allowing Pilot To Perform Visual Inspection

This final rule allows the visual inspections required by paragraph (g)(1) of this AD to be performed by an aircrew member holding at least a private pilot certificate. Performing a visual inspection to determine if the fuel filter by-pass indicator pop-up has been activated is not considered an action that must be performed by a certified person under 14 CFR 43.3. This authorization is an exception to our standard maintenance regulations.

Costs of Compliance

The FAA estimates that this AD affects 775 engines installed on helicopters 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
Visual inspection of fuel filter by-pass indicator.	1 work-hour × $85 per hour = $85	$0	$85	$65,875
Operational test of the fuel filter pre-blockage pressure switch.	3 work-hours × $85 per hour = $255	0	255	197,625

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace fuel filter pre-blockage pressure switch	2 work-hours × $85 per hour = $170	$225	$395

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

Authority for This Rulemaking

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

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

Regulatory Findings

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:

2021–13–03 Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca, S.A.): Amendment 39–21608; Docket No. FAA–2020–1180; Project Identifier MCAI–2020–00517–E.

(a) Effective Date

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

(b) Affected ADs

None.

(c) Applicability

This AD applies to Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca, S.A.) Arriel 2B, 2B1, 2C, 2C1, 2C2, 2S1 and 2S2 model turboshaft engines with a fuel filter pre-blockage pressure switch, part number 9 550 17 200 0, and serial number (S/N) 00001 to 12753, inclusive, and S/N A0001 to A0247, inclusive, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7321, Fuel Control/Turbine Engines.

(e) Unsafe Condition

This AD was prompted by reports from the manufacturer of non-conforming fuel filter pre-blockage pressure switches manufactured before December 2016. The FAA is issuing this AD to prevent the non-conformity of the fuel filter pre-blockage pressure switch, which can cause its non-activation in case of fuel system contamination, with consequent opening of the by-pass without indication in the cockpit. The unsafe condition, if not addressed, could result in uncommanded in-flight shut-down of the engine, an emergency autorotation landing on a single engine helicopter, or an uncommanded in-flight shut-down of both engines on a twin engine helicopter.

(f) Compliance

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

(g) Required Actions

(1) After the effective date of this AD, during the pre-flight inspection for the first flight of each day the engine is operated, perform a visual inspection of the fuel filter by-pass indicator to determine if the fuel filter by-pass indicator pop-up has been activated.

(2) Within the next 300 hydro-mechanical metering unit (HMU) operating hours or 180 days after the effective date of this AD, whichever occurs first, perform an operational test of the fuel filter pre-blockage pressure switch in accordance with Task 73–23–01–750–801–A01—Pre-Blockage Pressure Switch of the Fuel Filter Tests (Electrical), dated November 30, 2012, (the Task) from the Turbomeca Arriel 2 S1 Maintenance Manual.

(3) During any visual inspection required by paragraph (g)(1) of this AD, if the fuel filter by-pass indicator pop-up has been activated or, during the operational test required by paragraph (g)(2) of this AD, any discrepancy is detected as described by the Task, before next flight, replace the fuel filter pre-blockage pressure switch with a part eligible for installation.

(4) The actions required by paragraph (g)(1) of this AD may be performed by the owner/operator (pilot) holding at least a private pilot certificate, and must be entered into the aircraft records showing compliance with this AD, in accordance with 14 CFR 43.9 (a)(1) through (4) and 14 CFR 91.417(a)(2)(v). The records must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(h) Terminating Action

Passing the operational test (no failure detected) of the fuel filter pre-blockage pressure switch, as required by paragraph (g)(2) of this AD, or replacement of the fuel filter pre-blockage pressure switch with a part eligible for installation, constitutes a terminating action for the repetitive visual inspections required by paragraph (g)(1) of this AD for that engine.

(i) Definition

A part eligible for installation is a fuel filter pre-blockage pressure switch that is not listed in the Applicability, paragraph (c), of this AD, or a fuel filter pre-blockage pressure switch that has passed the operational test (no discrepancies detected) required by paragraph (g)(2) of this AD.

(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 ECO Branch, send it to the attention of the person identified in Related Information. You may email your request to: *ANE-AD-AMOC@faa.gov.*

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

(k) Related Information

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

(2) Refer to EASA AD 2019–0180, dated July 25, 2019, 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–2020–1180.

(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) Task 73–23–01–750–801–A01—Pre-Blockage Pressure Switch of the Fuel Filter Tests (Electrical), dated November 30, 2012, from the Turbomeca Arriel 2 S1 Maintenance Manual.

(ii) [Reserved]

(3) For Turbomeca service information identified in this AD, contact Safran Helicopter Engines, S.A., Avenue du 1er Mai, Tarnos, France; phone: +33 (0) 5 59 74 40 00.

(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: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 1, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–14520 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0456; Project Identifier MCAI–2021–00212–T; Amendment 39–21601; AD 2021–12–14]

RIN 2120–AA64

Airworthiness Directives; Yaborã Indústria Aeronáutica S.A. (Type Certificate Previously Held by Embraer S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–08–11, which applied to all Yaborã Indústria Aeronáutica Model ERJ 190–

300 and ERJ 190–400 airplanes. AD 2020–08–11 required revising the existing airplane flight manual (AFM) procedures associated with messages of smoke in the electronic bays presented on the respective engine indication and crew alerting system (EICAS). This AD continues to require revising the existing AFM procedures, and adds requirements for a terminating modification of the electrical wiring of the mid-electronic bay and backup smoke detectors; as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is incorporated by reference. This AD was prompted by a failure propagation test, which revealed that under certain conditions, the smoke detection system of the electrical bays erroneously indicated the presence of smoke via the respective EICAS messages. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective July 26, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 26, 2021.

The FAA must receive comments on this AD by August 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 National Civil Aviation Agency (ANAC), Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, BRAZIL, Tel: 55 (12) 3203–6600; Email: *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this IBR material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.* You may view this IBR 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 on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0456.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0456; 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, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Krista Greer, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued AD 2020–08–11, Amendment 39–19903 (85 FR 27112, May 7, 2020) (AD 2020–08–11), which applied to all Yaborã Indústria Aeronáutica Model ERJ 190–300 and ERJ 190–400 airplanes. AD 2020–08–11 required revising the existing AFM procedures associated with messages of smoke in the electronic bays presented on the respective EICAS. The FAA issued AD 2020–08–11 to provide the flightcrew with revised AFM procedures for responding to erroneous indications of smoke in the electrical bays presented on the EICAS. The AFM procedures are intended to prevent loss of all electrical digital current (DC) essential buses, causing loss of electrical power for critical systems of the airplane.

Actions Since AD 2020–08–11 Was Issued

Since the FAA issued AD 2020–08–11, the FAA has determined that it is necessary to mandate a modification to correct the root cause of erroneous indications of smoke in the electrical bays presented on the EICAS that will allow for removal of the AFM revision required by AD 2020–08–11. Production airplanes are not included in the applicability of this AD because the modification required by this AD is incorporated during production.

ANAC, which is the aviation authority for Brazil, has issued ANAC AD 2021–02–01, effective February 15, 2021; corrected February 23, 2021 (ANAC AD 2021–02–01) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI); to correct an unsafe condition for all Yaborã Indústria Aeronáutica Model ERJ 190–300 and ERJ 190–400 airplanes. ANAC AD 2021–02–01 superseded ANAC Emergency AD 2019–12–01, effective December 9, 2019 (which corresponds to FAA AD 2020–08–11).

This AD was prompted by a failure propagation test, which revealed that when complete loss of the electrical DC essential bus 2 was induced, the smoke detection system of the forward and aft electrical bays erroneously indicated the presence of smoke via the respective EICAS messages. When these messages are displayed, the existing AFM procedures require the flightcrew to turn off the essential electrical buses DC ESS BUS 1 and DC ESS BUS 3. The FAA is issuing this AD to address a loss of all electrical DC essential buses, and consequent loss of electrical power for critical systems of the airplane. See the MCAI for additional background information.

Explanation of Retained Requirements

Although this AD does not explicitly restate the requirements of AD 2020–08–11, this AD retains all of the requirements of AD 2020–08–11. Those requirements are referenced in ANAC AD 2021–02–01, which, in turn, is referenced in paragraph (g) of this AD.

Related Service Information Under 1 CFR Part 51

ANAC AD 2021–02–01 describes temporary revisions to the existing AFM procedures associated with messages of smoke in the electronic bays presented on the EICAS, and removal of those temporary revisions once a modification of certain electrical wiring is completed. ANAC AD 2021–02–01 also describes procedures for modification of electrical wiring of the mid-electronic bay and backup smoke detectors, which is terminating action for the temporary revisions to the AFM. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD because the FAA has evaluated all pertinent information and determined

the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Requirements of This AD

This AD requires accomplishing the actions specified in ANAC AD 2021–02–01 described previously, as incorporated by reference, 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 initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, ANAC AD 2021–02–01 is incorporated by reference in this AD. This AD, therefore, requires compliance with ANAC AD 2021–02–01 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Service information specified in ANAC AD 2021–02–01 that is required for compliance with ANAC AD 2021–02–01 is available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0456.

FAA's Justification and Determination of the Effective Date

There are currently no domestic operators of these products. Therefore, the FAA finds that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0456; Project Identifier MCAI–2021–00212–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 Krista Greer, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *krista.greer.@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.

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

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product
Retained action from AD 2020–08–11	1 work-hour × $85 per hour = $85	$0	$85
New actions	6 work-hours × $85 per hour = $510	0	510

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 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.

Adoption of 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) 2020–08–11, Amendment 39–19903 (85 FR 27112, May 7, 2020), and

■ b. Adding the following new AD:

2021–12–14 Yaborã Indústria Aeronáutica S.A. (Type Certificate Previously Held by Embraer S.A.): Amendment 39–21601; Docket No. FAA–2021–0456; Project Identifier MCAI–2021–00212–T.

(a) Effective Date

This airworthiness directive (AD) becomes effective July 26, 2021.

(b) Affected ADs

This AD replaces AD 2020–08–11, Amendment 39–19903 (85 FR 27112, May 7, 2020) (AD 2020–08–11).

(c) Applicability

This AD applies to Yaborã Indústria Aeronáutica S.A. (type certificate previously held by Embraer S.A.) Model ERJ 190–300 and ERJ 190–400 airplanes, certificated in any category, identified in Agência Nacional de Aviação Civil (ANAC) AD 2021–02–01, effective February 15, 2021; corrected February 23, 2021 (ANAC AD 2021–02–01).

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical power.

(e) Reason

This AD was prompted by a failure propagation test, which revealed that when complete loss of the electrical digital current (DC) essential bus 2 was induced, the smoke detection system of the forward and aft electrical bays erroneously indicated the presence of smoke via the respective engine indication and crew alerting system (EICAS) messages, and by the determination that a terminating modification is necessary to correct the root cause of the unsafe condition. The FAA is issuing this AD to address the potential loss of all electrical DC essential buses, and consequent loss of electrical power for critical systems of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2021–02–01.

(h) Exceptions to ANAC AD 2021–02–01

(1) Where ANAC AD 2021–02–01 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where ANAC AD 2021–02–01 refers to December 9, 2019 (the effective date of ANAC Emergency AD 2019–12–01), this AD requires using May 22, 2020 (the effective date of AD 2020–08–11).

(3) The ''Alternative Methods of Compliance (AMOC)'' section of ANAC AD 2021–02–01 does not apply to this AD.

(4) Where Part II, paragraph (b)(2), of ANAC AD 2021–02–01 specifies that after modification of the electrical wiring of the mid electronic bay and backup smoke detectors the temporary airplane flight manual (AFM) revisions ''must be removed,'' this AD requires removing the temporary AFM revisions before further flight after completing the modification required by Part II, paragraph (b)(1), of ANAC AD 2021–02–01.

(i) Other FAA 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 (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(j) Related Information

For more information about this AD, contact Krista Greer, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(k) 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) Agência Nacional de Aviação Civil (ANAC) AD 2021–02–01, effective February 15, 2021; corrected February 23, 2021.

(ii) [Reserved]

(3) For ANAC AD 2021–02–01, contact National Civil Aviation Agency, Aeronautical Products Certification Branch (GGCP), Rua Laurent Martins, n° 209, Jardim Esplanada, CEP 12242–431—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this IBR material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th 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 on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0456.

(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 *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on June 4, 2021.

Gaetano A. Sciortino,

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

[FR Doc. 2021–14612 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0207; Airspace Docket No. 21–ANM–6]

RIN 2120–AA66

Establishment of Class E Airspace; Missoula, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E domestic en route airspace extending upward from 1,200 feet above the surface at Missoula, MT. This airspace facilitates vectoring of instrument flight rules (IFR) aircraft and properly contains IFR aircraft operating on direct routes under the control of Salt Lake City Air Route Traffic Control Center (ARTCC) and Seattle ARTCC.

DATES: Effective 0901 UTC, October 7, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Missoula, MT, to ensure the safety and management of IFR operations in the National Airspace System.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 20468; April 20, 2021) for Docket No. FAA–2021–0207 to establish Class E airspace at Missoula, MT. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment, in favor of the proposed action, was received.

Subsequent to the publication of the NPRM, the FAA determined that the proposed Class E6 airspace for Missoula, MT included a minor overlap into the proposed Class E6 airspace for Great Falls, MT (86 FR 18485; April 9, 2021). To remove the overlapping airspace, an additional geographic point has been added to the Missoula, MT Class E6 airspace legal description. This change does not have a significant impact on the proposed airspace boundaries in the NPRM. The geographic point that has been added to the Final Rule's legal description is ''lat 47°41′18″ N, long 112°36′32″ W.''

Class E6 airspace designations are published in paragraph 6006 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

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

The Rule

This amendment to 14 CFR part 71 establishes Class E en route domestic airspace extending upward from 1,200 feet above the surface at Missoula, MT. This action provides controlled airspace to facilitate vectoring of IFR aircraft under the control of Salt Lake City and Seattle ARTCCs. The airspace also ensures proper containment of IFR aircraft operating on direct routes where the current en route structure is insufficient.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 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 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

ANM MT E6 Missoula, MT [New]

That airspace extending upward from 1,200 feet above the surface within an area beginning at lat 48°24′0.0″ N, long 115°44′57″ W, to lat 48°25′0.0″ N, long 113°35′21″ W, to lat 47°53′10″ N, long 113°35′0.0″ W, to lat 47°41′18″ N, long 112°36′32″ W, to lat 47°40′32.29″ N, long 112°32′46.33″ W, to lat 46°01′40.93″ N, long 112°32′45.82″ W, to lat 46°02′0.0″ N, long 113°20′0.0″ W, to lat 46°02′0.0″ N, long 115°0.0′0.0″ W, to lat 46°40′0.0″ N, long 115°0.0′0.0″ W, to lat 46°40′0.0″ N, long 115°45′0.0″ W, then to the point of beginning.

Issued in Des Moines, Washington, on July 1, 2021.

B.G. Chew,

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

[FR Doc. 2021–14564 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0208; Airspace Docket No. 21–ANM–5]

RIN 2120–AA66

Amendment of Class E Airspace; Missoula, MT; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The Federal Aviation Administration (FAA) is correcting a final rule that appeared in the **Federal Register** on June 16, 2021. The rule modified the Class E airspace extending upward from 1,200 feet above the surface at Missoula International Airport, Missoula, MT. The Final Rule inadvertently used the word ''about'' instead of ''above'' when describing the airspace area. This action corrects the legal description for the Class E airspace extending upward from 1,200 feet above the surface.

DATES: Effective 0901 UTC, August 12, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (86 FR 31907; June 16, 2021) for Docket FAA–2021–0208 amending the Class E airspace extending upward from 1,200 feet above the surface at Missoula International Airport, Missoula, MT. Subsequent to publication, the FAA identified an error in the wording used to describe this Class E airspace area. This action corrects that error.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, Amendment of the Class E Airspace; Missoula, MT, published in the **Federal Register** of June 16, 2021 (86 FR 31907), FR Doc. 2021–12662, is corrected as follows:

§ 71.1 [Corrected]

■ 1. On page 31908, in the third column, beginning with line 35, the legal description for ANM MT E5 is corrected to read:

ANM MT E5 Missoula, MT [Amended]

Missoula International Airport, MT

(Lat. 46°54′59″ N, long. 114°05′26″ W)

That airspace extending upward from 700 feet above the surface within 3.5 miles each side of the 311° bearing extending from the Class D 4.4-mile radius to 22.3 miles northwest of the airport, and 1.6 miles west and 4.3 miles east of the 179° bearing extending from the Class D 4.4-mile radius to 15.2 miles south of the airport, and that airspace extending upward from 1,200 feet above the surface within a 46-mile radius of the Missoula International Airport.

Issued in Des Moines, Washington, on July 1, 2021.

B.G. Chew,

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

[FR Doc. 2021–14553 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0211; Airspace Docket No. 21–ANM–7]

RIN 2120–AA66

Establishment of Class E Airspace; Mountain Home, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E domestic en route airspace extending upward from 1,200 feet above the surface at Mountain Home, ID. This airspace facilitates vectoring of instrument flight rules (IFR) aircraft and properly contains IFR aircraft operating on direct routes under the control of Salt Lake City Air Route Traffic Control Center (ARTCC).

DATES: Effective 0901 UTC, October 7, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Mountain Home, ID, to ensure the safety and management of IFR operations in the National Airspace System.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 21673; April 23, 2021) for Docket No. FAA–2021–0211 to establish Class E airspace at Mountain Home, ID. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E6 airspace designations are published in paragraph 6006 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

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

The Rule

This amendment to 14 CFR part 71 establishes Class E en route domestic airspace extending upward from 1,200 feet above the surface at Mountain Home, ID. This action provides controlled airspace to facilitate vectoring of IFR aircraft under the control of Salt Lake City ARTCC. The airspace also ensures proper containment of IFR aircraft operating on direct routes where the current en route structure is insufficient.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 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 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

ANM ID E6 Mountain Home, ID [New]

That airspace extending upward from 1,200 feet above the surface within an area beginning at lat. 43°05′36″ N, long 114°51′26″ W, to lat. 42°26′27″ N, long. 114°57′44″ W; to lat. 42°25′53″ N, long. 116°03′43″ W; to lat. 43°07′42″ N, long. 116°44′08″ W; to lat. 44°03′18″ N, long. 117°05′05″ W; to lat. 44°15′42″ N, long. 116°19''34'' W; to lat. 44°03′41″ N, long. 116°12′15″ W; to lat. 43°58′04″ N, long. 115°51′09″ W; to lat. 43°47′52″ N, long. 115°41′21″ W; to lat. 43°30′14″ N, long. 115°36′38″ W; to lat. 43°17′24″ N, long. 115°41′05″ W; to lat. 43°03′38″ N, long. 115°19′32″ W; then to the point of beginning.

Issued in Des Moines, Washington, on July 1, 2021.

B.G. Chew,

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

[FR Doc. 2021–14556 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2016–HA–0112]

RIN 0720–AB69

TRICARE: Extended Care Health Option (ECHO) Respite Care

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Department of Defense is amending the TRICARE regulation to allow an ECHO program beneficiary to receive, when authorized, up to sixteen (16) hours of respite care per month without a prerequisite to receive other authorized non-respite care during the same month. Currently, Active Duty Family Members who are eligible for the ECHO program can receive a maximum of 16 hours of respite care per month, in any calendar month in which the beneficiary receives other non-respite ECHO benefits (referred to as ''concurrent'' care). As the specific requirement for a concurrent ECHO benefit, which was originally implemented to ensure optimal medical management of the beneficiary's ECHO-qualifying condition, is no longer necessary and may serve as an inappropriate barrier to receipt of respite services for some families, this final rule will eliminate the concurrent ECHO benefit requirement and allow an ECHO beneficiary to receive up to a maximum of 16 hours of respite care per month, regardless of whether another ECHO benefit is received in the same month.

DATES: This rule is effective August 9, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Carmen DeLeon, Defense Health Agency, TRICARE Health Plan Division, Telephone 210–536–6004.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Regulatory History

The Department published a proposed rule in the **Federal Register** on August 17, 2018 (83 FR 41026–41029) to eliminate the requirement for a beneficiary to receive a concurrent ECHO benefit in order to qualify for respite care. This change will expand access to respite care services (as recommended by the Military Compensation and Retirement Modernization Commission (MCRMC)), allowing families to access those hours

without receiving another ECHO benefit during the same month the respite care is received.

B. Summary of Major Provisions

The Department of Defense (the Department) remains committed to supporting Service members and their family members with special needs. Together, the Office of Community Support for Military Families with Special Needs, the Services, and the Military Health System are working to enhance and improve support for these families, including everything from complex medical management to non-clinical case management and family support services. The Department is also committed to eliminating unnecessary requirements that act as barriers to care. The requirement to receive a concurrent ECHO benefit in order to be entitled to ECHO respite care was originally imposed as a medical management tool. We now conclude that this specific requirement is no longer necessary and may serve as an inappropriate barrier to receipt of respite services for some families. Respite services for ECHO-eligible covered beneficiaries may still be appropriate and necessary even when no other ECHO services are provided (*i.e.,* where all needed care is otherwise covered under the TRICARE Basic Program or under demonstration authority).

The elimination of the requirement for a simultaneous ECHO benefit will provide maximum flexibility to families without sacrificing the goal of ensuring the safe and effective management of the beneficiary's ECHO qualifying condition. First, we note that TRICARE beneficiaries with complex medical needs may receive case management services including medical management, disease management and chronic care coordination, under the TRICARE Basic Program, regardless of whether the beneficiary is an ECHO eligible beneficiary. As the TRICARE program has evolved over time, continuing to require an ECHO eligible beneficiary to receive a concurrent ECHO benefit as a medical management tool is no longer necessary. Based on our current program structure, beneficiaries should already be receiving medical management services and the receipt of any ECHO benefit, including ECHO respite care, provides an additional opportunity to ensure the safe and effective management of the beneficiary's qualifying condition. Furthermore, in accordance with 32 CFR 199.5(h)(3), all ECHO benefits, including ECHO respite care, require authorization prior to receipt of such benefits. Paragraph 199.5(i) discusses required documentation as a prerequisite to authorizing ECHO benefits. As a practical matter, the Home Health Aide (HHA) providing the respite services must document the health care services needed by the ECHO beneficiary in the absence of the family caregiver and the schedule for the services during the provision of respite care in order to ensure an appropriately trained provider is sent and the beneficiary's needs are met. Additional details regarding required documentation to be provided to the Managed Care Support Contractor and HHA for authorization of ECHO respite services will be published in the TRICARE Policy Manual available at *http://manuals.tricare.osd.mil.* We believe that this approach will provide greater flexibility and eliminate unnecessary barriers for families to access ECHO respite care services while still ensuring the safe and effective medical management of the beneficiary's qualifying condition(s).

C. Legal Authority for This Program

The ECHO program is authorized by 10 United States Code (U.S.C.) 1079(d)–(f), and has been implemented through regulation at 32 CFR 199.5 (available at *https://www.govregs.com/regulations/title32_chapterI_part199_section199.5*). Per 32 CFR 199.5(c)(7), ECHO beneficiaries are eligible for a maximum of 16 hours of respite care per month in any month during which the beneficiary otherwise receives an ECHO (other than the ECHO Home Health Care (EHHC)) benefit(s). This regulation is finalized under the authority of 5 U.S.C. 301 (available at *https://www.govregs.com/uscode/title5_partI_chapter3_subchapterI*), which allows the Secretary of Defense to prescribe regulations for the government; and 10 U.S.C. 1079(d) and (e) (available at *https://www.govregs.com/uscode/title10_subtitleA_partII_chapter55*), which directs the Secretary of Defense to establish a program to provide extended benefits for eligible active duty dependents, which may include the provision of comprehensive health care services, including case management services, to assist in the reduction of the disabling effects of a qualifying condition of an eligible dependent. The Department is authorized to provide ''respite care for the primary caregiver of the eligible dependent'' as one of the specifically enumerated extended benefits under the ECHO program pursuant to 10 U.S.C. 1079(e)(6).

II. Public Comments

Comments were received from thirty-one individuals, medical affiliated organizations, and military and veterans associations via *www.regulations.gov.* We have carefully considered all public comments, and specific matters raised by those comments are summarized below. We reaffirm the policies and procedures contained in the proposed rule and maintain the rationale presented in the preamble of the proposed rule.

A. Analysis of Public Comments

The government received many comments that were in favor of the elimination of the concurrent ECHO benefit requirement. Many comments also noted that a minimum increase of four hours to the current sixteen hours (total of twenty hours per month) was reasonable.

Response: Increasing the number of respite hours per month from 16 to 20 is a major change and under the law we must give the public notice and an opportunity for comment. Therefore, an increase in respite hours will not be incorporated under this final rule. A separate rule will be considered by the Department when further analysis of the appropriate number of hours of respite is conducted.

Two of these comments recommended consideration that the respite program be open to more providers than just HHAs as some beneficiaries do not require a home health nurse or aide to provide respite care to children with autism.

Response: Respite care consists of providing skilled and non-skilled services to a beneficiary such that in the absence of the primary caregiver, management of the beneficiary's ECHO qualifying condition and safety are provided. Therefore, 32 CFR part 1079 requires a TRICARE-authorized HHA provide the services under the ECHO program. This is critical to ensure the safety of our beneficiaries.

Twenty-four comments were received in which commenters requested that the ECHO respite benefit be aligned with the Medicaid Home and Community waiver per the 2015 MCRMC which asked that a transitional benefit be made available to cover families that are separating or retiring from active duty (AD) service.

Response: By law, ECHO is available only to ADFMs and therefore a transitional benefit to cover families that are separating or retiring from AD service would require legislation.

We received two comments indicating that there are several geographic areas

that cannot obtain service due to a lack of providers, or that providers have declined to accept a beneficiary when limited to 16 hours per month.

Response: As previously stated, in order to assure the quality of care for ECHO beneficiaries, all ECHO respite care services will be provided only by Medicare or Medicaid certified HHAs who have in effect at the time of services a valid agreement to participate in the TRICARE program. Consequently, ECHO respite services are available only in locations where there are Medicare or Medicaid certified HHAs.

Four comments included requests for the benefit to allow sibling care from the same HHA that is providing ECHO respite care.

Response: While this request is understandable, 32 CFR 199.5 requires respite care services be provided by a TRICARE-authorized HHA and are designed to provide health care services for the covered beneficiary. Child-care services for other members of the family is not authorized medical care.

One comment sought clarification on the amount of respite hours and impact on yearly cost, and specifically asked whether the respite hours would be incorporated into the yearly benefit limitations.

Response: Yes, by law, the cost of respite care under ECHO will be calculated into the yearly benefit. The Government's share of the total cost of providing such benefits in any year shall not exceed $36,000.

B. Provisions of the Final Rule

The final rule is consistent with the proposed rule. No changes were made to the rule text as a result of comments received; however, certain provisions discussed in the proposed rule have been deleted from the final rule (*e.g.,* increasing authorized hours beyond 16 per month).

III. Regulatory Analysis

A. Cost Estimate: No Concurrent Care Requirement and 16 Hours per Month Limit

Current Policy Baseline Costs—Baseline (current policy) respite care costs incurred for those ECHO beneficiaries were estimated using respite care in FY18 (the latest full fiscal year data available). Out of a total of 1,267 ECHO users diagnosed with ASD, there were 66 respite care users who incurred $48,022 in paid costs for respite care billing codes (S9122, S9123, and S9124). Of these 66 users, 17 incurred the maximum of 16 hours per month over an average of 1.7 months (total paid amount of $10,969) and 49 incurred an average of 11.3 hours per month over an average of 2.8 months (total paid amount of $37,053). Out of a total of 3,689 ECHO users with non-ASD diagnoses, there were 9 respite care users who incurred $19,533 in paid costs for the three respite care billing codes. Of these 9 users, 4 incurred the maximum of 16 hours per month over an average of 7.5 months (total paid amount of $12,262) and 5 incurred an average of 13.0 hours per month over an average of 4.4 months (total paid amount of $7,271). Because these users are not in the EHHC program, most of these expenditures were for respite-like services. As a result, FY18 baseline costs for ECHO respite care were $67,555 ($10,969 + $37,053 + $12,262 + $7,271; see Table 1).

Cost of an Expanded Non-Concurrent Respite Benefit—Incremental respite costs were estimated under the proposed policy change that would not require concurrent care for two groups of ECHO beneficiaries: (1) Those who used ECHO respite care in FY18 and (2) those who only used non-respite ECHO care in FY18. The costs associated with ADFMs using the Autism Care Demonstration (ACD), who are not currently using the respite care benefit, were also estimated. All of these ADFM beneficiaries using the ACD are enrolled in ECHO and would be eligible to use respite care under the non-concurrent policy change.

In estimating the potential costs of the policy change, beneficiaries who used ECHO respite care in FY18 were first examined. As discussed above, in FY18 there were a total of 75 respite care users: 66 diagnosed with ASD and 9 with non-ASD diagnoses. It was assumed that their average number of respite care hours per month and the paid amount per month would not change under the new benefit. However, it was also assumed that the average number of months that they would utilize respite care would increase because the number of respite care months after the change would now be unconstrained (up to a maximum of 12 months) due to the absence of concurrency. To estimate the average number of respite care months per user, FY18 data from the Comprehensive Autism Care Demonstration (ACD) was examined. It was determined that ADFM patients had an average (and median) of 8 months of care in the ACD during FY18. As a result, 8 months is a reasonable proxy for the number of months of respite care an average patient would use if the number of months were not constrained. Therefore, it was assumed that the average patient's family would use respite care services for 8 months on average. Baseline respite users were multiplied first by average months per year of respite care per user, then by average respite hours per month, and lastly by average paid amount per hour for respite care. This results in an estimated total of $182,235 in paid costs under the new benefit for baseline respite care users ($51,441 + $104,495 + $13,079 + $13,220).

Then, added costs for those beneficiaries currently using only non-respite ECHO care during FY18 were estimated. In order to estimate respite care user uptake rates under the expanded benefit, it is important to understand why current rates for non-EHHC ECHO users are so low (between 0.2 percent for patients not diagnosed with autism and 5 percent for patients diagnosed with autism). The National Respite Coalition Task Force has surveyed families in the civilian world on the reasons why respite care uptake is low. Five reasons possibly apply to ECHO beneficiaries: Restrictive eligibility criteria, lack of information about respite program availability, inadequate supply of trained providers, inability to relate to or trust non-family caregivers, and guilt. The Department concludes that a revised policy for ECHO respite care would be largely influenced by the first two reasons: The extent to which restricted eligibility criteria will be reduced (in our case concurrency will no longer be required) and the extent to which the current lack of information about ECHO's respite benefit is reduced. Consequently, the Department concludes that utilization rates under the revised ECHO respite benefit will largely be dependent upon (1) the fact that the respite benefit will now be available in all 12 months of the year independent of non-respite care ECHO use, and (2) the extent to which the new respite benefit would be promoted by the MCSCs, the Exceptional Family Member Program (EFMP), DHA, and related advocacy groups.

Some new beneficiaries may be drawn into the program because of the value of the new benefit (*i.e.,* that it can be used in any month). Also, others could be drawn to use respite care because of promotion of the benefit through various media by interested parties. The MCSCs, EFMP, advocacy groups (*e.g.*, Autism Speaks) and DHA will likely provide information by means of newsletters, web page postings, and other media. This information would then spread by word of mouth and on-line chat groups. While some studies have suggested respite care uptake rates of 15 to 20 percent, it is likely that these

rates are too high for the TRICARE ECHO population given its low level of use today. Given that current uptake rates are less than 1 percent for the ECHO population not diagnosed with autism and 5 percent for the autism-diagnosed population, it is believed that with the new information disseminated regarding the benefit, uptake rates of between 1 and 5 percent (3 percent mid-point) and 5 and 10 percent (7.5 percent mid-point) for the two groups respectively are reasonable assumptions. These assumptions imply that, in FY18, 90 non-respite ECHO users diagnosed with ASD (0.075 * 1,201) and 110 non-respite ECHO users with non-ASD diagnoses (0.03 * 3,680) would have used respite care if the expanded benefit had been available. Assuming that these non-respite care ECHO users take on the same average respite care utilization and cost characteristics of their respite care user counterparts (separately for those diagnosed with ASD and those with other diagnoses) assumed under the new benefit, it is estimated that these new respite care ASD users would have had $212,753 in incremental costs and non-ASD users would have had $322,526 in respite care costs, for a total of $535,279, if the benefit had been available during FY18.

Finally, the additional respite care costs for the 11,138 patients who used the ACD and who were eligible for (but did not use) the ECHO program during FY18 was estimated. Under the proposed change, these patients would be able to use ECHO during any month of the year, and for the sole purpose of receiving respite care. To estimate costs for this group, the same approach noted above was used for ECHO program participants diagnosed with ASD who did not use respite care. First, it was assumed that 7.5 percent of the 11,138 ACD patients, or 835 patients, would use respite care services under the new policy. Assuming that these 835 ACD patients would have the same average respite care utilization and cost characteristics of their ECHO user counterparts diagnosed with ASD assumed under the new benefit, it was estimated that these ACD users would have had $1,973,055 in additional respite care costs, if the benefit had been available during FY18.

In summary, it is estimated that total costs of the new benefit would have been $2,690,569 (or $182,235 + $535,279 + $1,973,055) if the benefit had been available during FY18. The incremental costs would be $2,623,014 in FY18 which are equal to total new respite program costs minus baseline costs.

B. Benefits

ADFM ECHO beneficiaries would be able to use an expanded respite benefit that would allow them to obtain the benefit in any month of the year regardless of the use of non-respite ECHO services. Under this rule, ECHO EHHC beneficiaries would continue to receive a more generous respite care benefit (a maximum of 8 hours per day, 5 days a week).

C. Alternatives

Two alternatives, besides this rulemaking action, were considered.

- No action. This alternative would not allow TRICARE to expand access to respite care services (as recommended by the Military Compensation and Retirement Modernization Commission (MCRMC)), allowing families to access those hours without receiving another ECHO benefit during the same month the respite care is received. The results of this alternative are not preferred.
- Next Best Alternative. Expand the respite care benefit by increasing the Monthly Respite Maximum from 16 to 20 hours. Under this alternative, which assumes that both the concurrent care requirement is eliminated and the cap on monthly hours would be increased from 16 to 20 hours, health care costs are estimated as nearly $3.2 million in FY20. This alternative is not preferred.
- The Preferred Alternative is the final rule action being taken.

IV. Regulatory Procedures

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

Executive Orders (E.O.s) 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. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year). This rulemaking is neither ''economically significant'' as measured by the $100 million threshold, nor is it otherwise significant.

Congressional Review Act, 5 U.S.C. 804(2)

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

Public Law 96–354, ''Regulatory Flexibility Act'' (RFA), (Title 5, U.S.C., Sec. 601)

The Assistant Secretary of Defense for Health Affairs certifies that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Public Law 104–4, Sec. 202, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $140 million. This final rule will not mandate any requirements for state, local, or tribal governments or the private sector.

Public Law 96–511, ''Paperwork Reduction Act'' (Title 44, U.S.C., Chapter 35)

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3502–3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized. TRICARE ECHO respite care providers will be coding and filing claims in the same manner as they currently are with TRICARE.

Executive Order 13132, ''Federalism''

This rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES CHAMPUS

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. In § 199.5, revise paragraph (c)(7) introductory text to read as follows:

§ 199.5 TRICARE Extended Care Health Option (ECHO).

* * * * *

(c) * * *

(7) *Respite care.* TRICARE beneficiaries enrolled in ECHO are eligible for a maximum of 16 hours of respite care per month. Respite care is defined in § 199.2. Respite care services will be provided by a TRICARE-authorized HHA and will be designed to provide health care services for the covered beneficiary. The benefit will not be cumulative, that is, any respite hours not used in one month will not be carried over or banked for use on another occasion.

* * * * *

Dated: July 2, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–14614 Filed 7–8–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2021–OESE–0045]

Final Priorities—Effective Educator Development Division

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final priorities.

SUMMARY: The Department of Education (Department) announces priorities for the following programs of the Effective Educator Development Division (EED): Teacher and School Leader Incentive Grants (TSL), Assistance Listing Number (ALN) 84.374A; Supporting Effective Educator Development (SEED), ALN 84.423A; and Teacher Quality Partnership (TQP), ALN 84.336S. We may use these priorities for competitions in fiscal year (FY) 2021 and later years. We propose these priorities to focus on educator development, leadership, and diversity in the various EED programs in order to improve the quality of teaching and school leadership.

DATES: These priorities are effective August 9, 2021.

FOR FURTHER INFORMATION CONTACT: Orman Feres, U.S. Department of Education, 400 Maryland Avenue SW, Room 3C124, Washington, DC 20202. Telephone: (202) 453–6921. Email: *orman.feres@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:

Purpose of Program: This notice identifies final priorities for use in three Department programs: TSL, SEED, and TQP. The purpose of TSL is to assist States, local educational agencies, and nonprofit organizations to develop, implement, improve, or expand comprehensive performance-based compensation systems (PBCS) or human capital management systems (HCMS) for teachers, principals, and other school leaders (educators) (especially educators in high-need schools who raise student academic achievement and close the achievement gap between high- and low-performing students). In addition, a portion of TSL funds may be used to study the effectiveness, fairness, quality, consistency, and reliability of such systems. The SEED program provides funding to increase the number of highly effective educators by supporting the implementation of evidence-based practices that prepare, develop, or enhance the skills of educators. SEED grants allow eligible entities to develop, expand, and evaluate practices that can serve as models to be sustained and disseminated. The purposes of the TQP program are to improve student achievement; improve the quality of prospective and new teachers by improving the preparation of prospective teachers and enhancing professional development activities for new teachers; hold teacher preparation programs at institutions of higher education accountable for preparing teachers who meet applicable State certification and licensure requirements; and recruit highly qualified individuals, including minorities and individuals from other occupations, into the teaching profession.

Program Authority: 20 U.S.C. 1221e–3. TSL: Sections 2211–2213 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), 20 U.S.C. 6631–6633. SEED: Section 2242 of the ESEA, 20 U.S.C. 6672. TQP: Sections 200–204 of the Higher Education Act of 1965, as amended, 20 U.S.C. 1021–1022c.

We published a notice of proposed priorities (NPP) for these programs in the **Federal Register** on April 20, 2021 (86 FR 20471). The NPP contained background information and our reasons for proposing the particular priorities.

Except for minor editorial and technical revisions, there are no differences between the proposed priorities and these final priorities.

Public Comment: In response to our invitation in the NPP, we received 31 comments, 23 of which were relevant to the proposed priorities and 8 of which were not relevant to the proposed priorities and were not considered in the analysis. Of the 23 comments addressing the proposed priorities, 7 expressed support for the proposed priorities but either offered no specific recommendations to revise them or offered broad recommendations for strengthening the educator workforce that were outside the scope of these proposed priorities. The remaining 16 comments either expressed disagreement or broadly agreed while offering suggestions to strengthen the proposed priorities. Responses to these comments are found in the *Analysis of the Comments and Changes* below.

Analysis of the Comments and Changes: An analysis of the comments and of any changes to the proposed priorities follows. Generally, we do not address technical and other minor changes, or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raise concerns not directly related to the NPP.

Comment: In response to Priority 1—Supporting Educators and Their Professional Growth, one commenter suggested that encouraging educators to pursue advanced credentials, such as Master's degrees, may not necessarily lead to improvements in educator effectiveness and may produce unintended incentives for educators to leave the profession.

Discussion: We appreciate the comment regarding the potential limited impact on educator effectiveness and potential disincentives to educator retention that could result from encouraging teachers to pursue advanced credentials. Creating or enhancing professional growth

opportunities for educators is a chief component of the Administration's approach to ensuring that students from low-income backgrounds, students of color, students with disabilities, and other historically underserved students have equal access to qualified, experienced, and effective educators. The concerns outlined by the commenter are precisely the reasons why this priority promotes a holistic approach to supporting teachers and school leaders. The priority not only targets increased numbers of teachers with advanced credentials, which, in addition to a Master's Degree, may include National Board Certification or an additional credential, such as to teach English learners or students with special needs. It also promotes establishment of career ladders, improved pay systems, targeted professional development and a range of other strategies aimed at improving the educator workforce. We think that advanced credential attainment is an important part of this holistic strategy. Thus, we do not think that it is necessary to revise the proposed priorities to address this specific need.

Changes: None.

Comment: In response to Priority 1—Supporting Educators and Their Professional Growth, one commenter recommended that we focus on raising teacher salaries to be commensurate with that of other professionals whose roles require specialized training.

Discussion: We appreciate the comment regarding economic concerns facing educators and low teacher salaries may pose potential barriers to diverse candidates entering the educator profession. While we agree with the commenters on the need for educators' salaries to reflect the significance of their roles, we note that these priorities focus on preparing educators with the knowledge, skills, and supports needed to support the personal and academic growth of all students. We note one of the programs intended for potential use of these priorities, TSL, provides applicants with flexibility to propose innovative interventions aimed at enhancing educators' compensation based on their performance. For this reason, we do not think that it is necessary to revise the proposed priorities to address teachers' salaries.

Changes: None.

Comment: In response to Priority 2—Increasing Educator Diversity, one commenter cautioned that factors such as the wealth gap and income inequality along racial lines may lead to difficulty hiring diverse educators.

Discussion: We appreciate the comment regarding economic concerns facing educators and how they may pose potential barriers to diverse candidates entering the educator profession. We note that this priority has been established, due in part to the barriers to achieving a diverse educator workforce the commenter identified. We also note that this priority seeks to promote a holistic approach to attracting and retaining teachers and school leaders and we encourage districts and localities to leverage the opportunities afforded under this priority to design evidence-based and promising approaches to attracting diverse educator candidates. For this reason, we do not think that it is necessary to revise the proposed priority.

Changes: None.

Comment: Multiple commenters expressed support for both priorities, while suggesting a range of specific revisions. One commenter recommended changes to emphasize the importance of antibias and antiracist education to our existing workforce. On the topic of cultural responsiveness, multiple commenters cited research emphasizing the importance of culturally responsive school leadership and recommended specific revisions to highlight the importance of culturally responsive and culturally sustaining teaching practices. Another commenter recommended changes to both priorities to promote development and diversification of school leaders. With regard to professional development and professional learning of educators, one commenter recommended that the Department focus on learning communities, leadership, resources, data, learning designs, implementation, and outcomes. Another commenter noted the significant role of traditional educator preparation programs in advancing the goals of these priorities, while another commenter, focusing on the SEED program, recommended that we revise the priorities to more clearly highlight the role of high-quality, non-traditional educator preparation programs. A separate commenter recommended that we revise the priorities to emphasize the long-term sustainability of project activities implemented under these priorities. Additionally, one commenter stressed the importance of prioritizing grow-your-own recruitment approaches.

Discussion: We appreciate each commenter's suggestions and recognize the significance of the specific areas they recommend be emphasized in the proposed priorities. We note that several of these suggested items, such as ''grow your own'' programs, diversification of school leaders, and placing an emphasis on data and outcomes, are directly addressed in the priorities. We also acknowledge and appreciate the other suggestions made by commenters that highlight specific strategies or activities that could be specified in the priority. We note that these priorities are intended for use in discretionary grant programs and are designed to offer districts and localities flexibility to shape their local instructional programming around innovative initiatives that meet their distinct needs. We think that the priorities, as written, provide an equal measure of specificity and flexibility for prospective applicants to address the goals of supporting educators and their professional growth, as well as increasing educator diversity. Finally, we note that these suggested activities are already allowable under these programs, in addition to other programs funded by the Department, and are reflective of the Department's overall vision for the improvement of the educator workforce.

Upon further review, the Department believes that additional clarity would be helpful for applicants with respect to their plans to implement educator diversity practices. We are revising Priority 2 to combine and clarify the activities in proposed paragraphs (a) and (h).

Changes: In Priority 2, we have removed proposed paragraphs (a) and (h) and added a new paragraph (g) that encompasses activities related to data systems, timelines, and action plans for promoting educator and school leader diversity.

Comment: Multiple commenters expressed support for the proposed priorities but recommended we add language that specifically references sexual orientation, gender identity, and gender expression to add clarity around what is meant by the term ''diversity.''

Discussion: We appreciate the importance of being clear about the meaning of ''diversity.'' The Department has chosen to use the term ''diversity'' to describe and embrace all students and educators without exception. Thus, we do not think that it is necessary to revise the priorities in response to these specific recommendations.

Changes: None.

Final Priorities:

Priority 1—Supporting Educators and Their Professional Growth.

Projects that are designed to increase the number and percentage of well-prepared, experienced, effective, and diverse educators—which may include one or more of the following: Teachers, principals, paraprofessionals, or other school leaders as defined in section 8101(44) of the ESEA—through

evidence-based strategies (as defined in 34 CFR 77.1 or the ESEA) incorporating one or more of the following:

(a) Adopting, implementing, or expanding efforts to recruit, select, prepare, support, and develop talented, diverse individuals to serve as mentors, instructional coaches, principals, or school leaders in high-need schools (as may be defined in the program's authorizing statute or regulations) who have the knowledge and skills to significantly improve instruction.

(b) Implementing practices or strategies that support high-need schools (as may be defined in the program's authorizing statute or regulations) in recruiting, preparing, hiring, supporting, developing, and retaining qualified, experienced, effective, diverse educators.

(c) Increasing the number of teachers with State or national advanced educator certification or certification in a teacher shortage area, as determined by the Secretary, such as special education or bilingual education.

(d) Providing high-quality professional development opportunities to all educators in high-need schools (as may be defined in the program's authorizing statute or regulations) on meeting the needs of diverse learners, including students with disabilities and English learners.

Proposed Priority 2—Increasing Educator Diversity.

Under this priority, applicants must develop projects that are designed to improve the recruitment, outreach, preparation, support, development, and retention of a diverse educator workforce through adopting, implementing, or expanding one or more of the following:

(a) High-quality, comprehensive teacher preparation programs that have a track record of attracting, supporting, graduating, and placing underrepresented teacher candidates, and that include one year of high-quality clinical experiences (prior to becoming the teacher of record) in high-need schools (as may be defined in the program's authorizing statute or regulations).

(b) High-quality, comprehensive teacher preparation programs in Historically Black Colleges and Universities (eligible institutions under part B of title III and subpart 4 of part A title VII of the HEA), Hispanic Serving Institutions (eligible institutions under section 502 of the HEA), Tribal Colleges and Universities (eligible institutions under section 316 of the HEA), or other Minority Serving Institutions (eligible institutions under title III and title V of the HEA) that include one year of high-quality clinical experiences (prior to becoming the teacher of record) in high-need schools (as may be defined in the program's authorizing statute or regulations) and that incorporate best practices for attracting, supporting, graduating, and placing underrepresented teacher candidates.

(c) Reforms to teacher preparation programs to improve the diversity of teacher candidates, including changes to ensure underrepresented teacher candidates are fully represented in program admission, completion, placement, and retention as educators.

(d) Educator candidate support and preparation strategies and practices focused on underrepresented teacher candidates, and which may include ''grow your own programs,'' which typically recruit middle or high school students, paraprofessionals, or other school staff and provide them with clear pathways and intensive support to enter into the teaching profession.

(e) Professional growth and leadership opportunities for diverse educators, including opportunities to influence school, district, or State policies and practices in order to improve educator diversity.

(f) High-quality professional development on addressing bias in instructional practice and fostering an inclusive, equitable, and supportive workplace and school climate for educators.

(g) Data systems, timelines, and action plans for promoting inclusive and bias-free human resources practices that promote and support development of educator and school leader diversity.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use these priorities, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things

and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing the final priorities only on a reasoned determination that their benefits will justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on an analysis of anticipated costs and benefits, we believe that the final priorities are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Regulatory Flexibility Act Certification: The Secretary certifies that this regulatory action does not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The small entities that this regulatory action will affect are school districts, nonprofit organizations, and for-profit organizations. Of the impacts we estimate accruing to grantees or eligible entities, all are voluntary and related mostly to an increase in the number of applications prepared and submitted annually for competitive grant competitions. Therefore, we do not believe that the priorities will significantly impact small entities beyond the potential for increasing the likelihood of their applying for, and receiving, competitive grants from the Department.

Paperwork Reduction Act of 1995: The priorities contain information collection requirements that are approved by OMB under OMB control number 1894–0006 and 1810–0758; the priorities do not affect the currently approved data collection.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

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.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021–14713 Filed 7–8–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2020–OESE–0199]

Final Priority and Definition—Teacher and School Leader Incentive (TSL) Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final priority and definition.

SUMMARY: The Department announces one priority and one definition under the Teacher and School Leader Incentive Program (TSL), Assistance Listing Number 84.374A. The Department may use this priority and definition for competitions in fiscal year (FY) 2021 and later years. We take this action to make program improvements based on lessons learned over the last decade and to improve program outcomes.

DATES: The priority and definition are effective August 9, 2021.

FOR FURTHER INFORMATION CONTACT: Orman Feres, U.S. Department of Education, 400 Maryland Avenue SW, Room 3C124, Washington, DC 20202. Telephone: (202) 453–6921. Email: *orman.feres@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:

Purpose of Program: The purpose of TSL is to assist States, local educational agencies (LEAs), and nonprofit organizations to develop, implement, improve, or expand comprehensive performance-based compensation systems (PBCS) or human capital management systems (HCMS) for

teachers, principals, and other school leaders (educators) (especially educators in High-Need Schools who raise student academic achievement and close the achievement gap between high- and low-performing students). In addition, a portion of TSL funds may be used to study the effectiveness, fairness, quality, consistency, and reliability of such systems.

Program Authority: Sections 2211–2213 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), 20 U.S.C. 6631–6633.

A notice of proposed priorities (NPP) for this program was published in the **Federal Register** on April 9, 2021 (86 FR 18519). The NPP contained background information and our reasons for proposing the priority and definition.

Except for minor editorial and technical revisions, there are no differences between the proposed priority and definition and the final priority and definition.

Public Comment: In response to our invitation in the NPP, two comments were received, neither of which were relevant to the proposed priority and definition. The Secretary appreciates the public's interest in this program and the comments received in response to the NPP. However, we do not address general comments that raise concerns not directly related to the NPP.

Final Priority

High-Need Schools.

Under this priority, eligible applicants must concentrate proposed activities on teachers, principals, or other school leaders serving in High-Need Schools.

In order to demonstrate that the TSL project is concentrated in High-Need Schools, the applicant must—

(a) Provide the requested data in paragraph (c) of this priority to demonstrate that at least the majority of the schools participating in the proposed project are High-Need Schools and describe how the TSL-assisted grant activities are focused on those schools;

(b) Include a list of all schools in which the proposed TSL-funded project would be implemented and indicate which schools are High-Need Schools; and

(c) Provide the most recently available school-level data supporting each school's designation as a High-Need School.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Definition

The Assistant Secretary establishes the following definition for this program. We may apply this definition in any year in which this program is in effect.

High-Need School means a school with 50 percent or more of its enrollment from low-income families as calculated using—

(1) The number of children eligible for a free or reduced-price lunch under the National School Lunch Program (NSLP) (or, if an LEA does not participate in the NSLP, comparable data from another source such as a survey);

(2) If an LEA has one or more schools that participate in the Community Eligibility Provision (CEP) of the NSLP, for any of its schools (*i.e.,* CEP and non-CEP schools), the method in paragraph (1) of this definition or an alternative method approved by the Department; and

(3) For middle and high schools, data from feeder schools that can establish that the middle or high school is a High-Need School under paragraph (1) or (2) of this definition.

This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use this priority and definition, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or

provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this final priority and definition only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

The Department believes that this regulatory action will not impose significant costs on eligible entities, whose participation in our programs is voluntary, and costs can generally be covered with grant funds. As a result, the priority and definition will not impose any particular burden except when an entity voluntarily elects to apply for a grant. The benefits of the priority and definition will outweigh any associated costs because they will help ensure that the Department's TSL grant program selects high-quality applicants to implement activities that are designed to address High-Need Schools.

Regulatory Flexibility Act Certification: The Secretary certifies that this regulatory action does not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The small entities that this regulatory action would affect are school districts, nonprofit organizations, and for-profit organizations. Of the impacts we estimate accruing to grantees or eligible entities, all are voluntary and related mostly to an increase in the number of applications prepared and submitted annually for competitive grant competitions. Therefore, we do not believe that the priority and definition would significantly impact small entities beyond the potential for increasing the likelihood of their applying for, and receiving, competitive grants from the Department.

Paperwork Reduction Act of 1995: The priority and definition contain information collection requirements that are approved by OMB under OMB control number 1810–0758; the priority and definition do not affect the currently approved data collection. An FY 2021 competition would require applicants to complete and submit an application for Federal assistance using Department standard application forms. As a part of the application submission, respondents, who are LEAs, State educational agencies, the Bureau of Indian Education, nonprofit or for-profit organizations, or a combination thereof, will submit information demonstrating that each school included in the TSL-assisted project is a High-Need school. We estimate that for the FY 2021 TSL competition and later competitions, each applicant will spend approximately 87 hours of staff time to address the priority and definition. Based on the number of applications the Department received in the FY 2020 TSL competition, we expect to receive approximately 100 applications for these funds. The total number of hours for all expected applicants to address this priority and definition is an estimated 8,700 hours.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

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.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021–14712 Filed 7–8–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

RIN 1801–AA24

Final Requirements; American Rescue Plan Act Homeless Children and Youth Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final requirements.

SUMMARY: The Department of Education (Department) establishes requirements for the Homeless Children and Youth program (ARP–HCY), under section 2001(b)(1) of the American Rescue Plan Act of 2021 (ARP Act). These requirements are intended to clarify program requirements and streamline and clarify the process for State educational agencies (SEAs) to award subgrants to local educational agencies (LEAs).

DATES: These final requirements take effect July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Deborah Spitz, U.S. Department of Education, 400 Maryland Avenue SW, Room 3W200, Washington, DC 20202. Telephone: (202) 260–3793. Email: *deborah.spitz@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:

Purpose of Program: The ARP–HCY program provides a total of $800 million for the Secretary of Education (Secretary) to use for the purposes of identifying homeless children and youth and providing homeless children and youth with wrap-around services in light of the challenges of the COVID–19 pandemic and assistance needed to enable homeless children and youth to attend school and participate fully in school activities. These funds may be used by States to address urgent needs of children and youth experiencing homelessness—including academic, social, emotional, and mental health needs. The funds will also be used by States and local educational agencies (LEAs) to increase capacity by hiring staff, dedicating resources, and planning partnerships with community-based organizations, among other strategies.

Program Authority: Section 2001(b)(1) of the ARP Act, Public Law 117–2, March 11, 2021.

Background: The ARP–HCY program provides $800 million to fund vital assistance to homeless children and youth. On April 26, 2021, the Department released approximately 25 percent of these funds (ARP Homeless I) as a supplement to SEAs' grants under the Education for Homeless Children and Youths (EHCY) program authorized by Title VII–B of the McKinney-Vento Homeless Assistance Act (McKinney-Vento Act). SEAs and LEAs may use ARP Homeless I funds for a wide range of services and activities, including tutoring, transportation, coordination with housing, health and social services, counseling, and other supports for academic, social, emotional, and mental health needs, to address the urgent needs of homeless children and youth. Funds may also be used to build SEA and LEA capacity to effectively administer these funds. SEAs were encouraged to use the initial disbursement of funds to supplement existing EHCY grants, and many have done so or are in the process of doing so.

The Secretary is establishing final requirements for the second disbursement of ARP–HCY funds (ARP Homeless II) related to program requirements and the formula for the SEAs' distribution of these funds to LEAs.

In paragraph (a) of the final requirements, the Department provides that the requirements apply to an SEA's ARP Homeless II allocation.

Paragraph (b) provides that the funds are subject to all provisions of Title VII–B of the McKinney-Vento Act, except as provided in paragraph (c), which governs subgrants to LEAs. The Department establishes this requirement because the EHCY program supports an existing infrastructure of State Coordinators in States and local liaisons in LEAs. Furthermore, the allowable activities under this program are broadly defined and meet a wide range of academic, social, emotional, and mental health needs of children and youth experiencing homelessness. Creating a program with different requirements and a different infrastructure is likely to result in confusion and duplication of efforts, at a time when students urgently need support.

Paragraph (c) of the requirements contains a formula for the SEAs' distribution of funds to LEAs from the funds remaining after the SEA State activities reservation (which may be up to 25 percent of the SEA's award, consistent with section 722(e)(2) of the McKinney-Vento Act). The McKinney-Vento Act includes a statutory requirement that States distribute at least 75 percent of funds to LEAs. It also requires SEAs to award these funds competitively to LEAs using criteria based on need and quality. This requirement ensures that the limited EHCY program funds that have historically been appropriated under this program are distributed to the LEAs with the greatest need but has also resulted in only approximately 25 percent of LEAs receiving EHCY subgrants. Given the substantial increase in funding for supports and services for homeless children and youth under the ARP Act, the need for rapid distribution to meet urgent student needs, and the importance of serving students experiencing homelessness in communities that have not historically participated in the EHCY subgrant program, the Department establishes a requirement in paragraph (c)(1) that the SEA distribute the ARP Homeless II funds to LEAs by formula rather than competition. Requiring SEAs to distribute the ARP Homeless II funds to LEAs by formula will ensure that the vast majority of LEAs will be able to receive subgrants.

The formula is based equally on the proportional share of an LEA's allocation under Title I, Part A of the Elementary and Secondary Education Act of 1965 (ESEA) for the most recent fiscal year, and the LEA's proportional share of the number of homeless children and youth identified by each LEA relative to all LEAs in the State, using the greater of the number of homeless children and youth in either the 2018–19 or 2019–20 school year in each LEA. This formula ensures a balance in the distribution of funds to focus on the needs of the LEAs, considering both the LEA's number of low-income students and the number of homeless children and youth. In addition, allowing the use of either the 2018–19 school year or 2019–20 school year homeless counts takes into consideration the potential for undercounting in the 2019–20 school year due to COVID–19 by allowing LEAs to use the greater of the two numbers.

The Department establishes in paragraph (c)(2) that an LEA must have an allocation of at least $5,000 under the formula to be eligible for an ARP Homeless II subgrant on its own. This $5,000 minimum will enable each subgrantee to have sufficient ARP Homeless II funds to address the needs of homeless children and youth. We chose as the threshold the smallest amount reasonable to sufficiently implement a local program. If an LEA's allocation would be less than $5,000, in order to receive an ARP Homeless II subgrant, the LEA must join a consortium of LEAs in which the sum of its members' allocations meets the $5,000 threshold. For LEAs with an allocation less than $5,000, the rule encourages the use of consortia to create favorable economies of scale.

Final Requirements: The Secretary establishes the following final requirements for the ARP–HCY program.

(a) Applicability. These requirements apply to a State educational agency's (SEA) second allocation of funds from the Department of Education under section 2001(b)(1) of the American Rescue Plan Act of 2021 (ARP Homeless II).

(b) Program administration. The funds described in paragraph (a) are subject to all provisions of Title VII–B of the McKinney-Vento Homeless Assistance Act, except as provided in paragraph (c).

(c) Subgrants to local educational agencies (LEAs).

(1) Each SEA must award subgrants by allocating not less than 75 percent of the funds it receives under the ARP Homeless II program to LEAs as follows:

(i) 50 percent in proportion to the amount that each LEA received under Part A of Title I of the Elementary and Secondary Education Act of 1965, as amended, for the most recent fiscal year; and

(ii) 50 percent in proportion to the number of homeless children and youth

identified by each LEA relative to all LEAs in the State, using the greater of the number of homeless children and youth in either the 2018–19 or 2019–20 school year in each LEA.

(2) An SEA may not make a subgrant to an LEA under paragraph (c)(1) if the amount of such subgrant would be less than $5,000. An LEA that does not meet this minimum allocation requirement may receive a subgrant only as part of a consortium with other LEAs if the total of their combined allocations is at least $5,000.

(3) For the purpose of paragraph (c), a consortium means a subgrantee that consists of more than one LEA.

Waiver of Notice and Comment Rulemaking and Delayed Effective Date

Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed requirements. However, the APA provides that an agency is not required to conduct notice and comment rulemaking when the agency for good cause finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B). Here, there is good cause to waive notice and comment rulemaking due to the urgent needs of children and youth experiencing homelessness in light of the national pandemic, as going through the full rulemaking process would delay the awarding of these grants to SEAs and LEAs.

The good cause exception is appropriate ''in emergency situations or where delay could result in serious harm.'' *See Jifry* v. *FAA,* 370 F.3d 1174, 1179 (D.C. Cir. 2004) (internal citations omitted). ''The public interest prong of the good cause exception to the APA notice and comment requirement is met only in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest.'' *Mack Trucks Inc.* v. *E.P.A.,* 682 F.3d 87, 95 (D.C. Cir. 2012).

The ARP–HCY funds are intended to support the specific and urgent needs of homeless children and youth due to the extraordinary impact of the pandemic on students experiencing homelessness, including reduced identification of such students, decreased enrollment in school, interrupted classroom instruction, and challenges navigating services for shelter/housing, clothing and school supplies, food, and child care. Due to the emergency nature of this situation, there is not time for public notice and comment. By establishing these requirements now, SEAs and LEAs may more quickly and effectively plan for and use ARP–HCY funds to address the needs of homeless children and youth. Establishing the final rule now will give SEAs the opportunity to award ARP Homeless II funds to LEAs by the start of the 2021–22 school year (which can be early August in some States). During the school closures following March 2020, many students experiencing homelessness became disengaged, stopped attending regularly or submitting assignments, became chronically absent, or dropped out. Those students will need intensive educationally related support services beginning from the first day of the new school year. A delay of even two months to the final requirement and disbursement of funds for ARP Homeless II will prolong the interruptions in learning for hundreds of thousands of students experiencing homelessness during the pandemic. The beginning of the school year is a critical time for identifying and connecting students experiencing homelessness to remediation and support services. For example, if funds are not awarded to LEAs before September, it will be difficult for schools to place students who are identified as experiencing homelessness in classes at the appropriate grade level, delaying access to critical support services and prolonging interruption in learning caused by the pandemic.

The APA also requires that regulations be published at least 30 days before their effective date, unless the agency has good cause to implement its regulations sooner (5 U.S.C. 553(d)(3)). As discussed above, because the ARP–HCY funds are needed to address the immediate needs of homeless children and youth, the Secretary also has good cause to waive the 30-day delay in the effective date of these requirements under 5 U.S.C. 553(d)(3).

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a significant regulatory action as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or Tribal governments or communities in a material way (also referred to as ''economically significant'' regulations);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This regulatory action is an economically significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a ''major rule,'' as defined by 5 U.S.C. 804(2).

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account, among other things, and to the extent practicable, the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or providing information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these

techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

The Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action, and we are issuing these final requirements only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows and the reasons stated elsewhere in this document, the Department believes that the final requirements are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, or Tribal governments in the exercise of their governmental functions.

In this regulatory impact analysis, we discuss the need for regulatory action, the potential costs and benefits, and net budget impacts. The main benefit of this regulatory action is that funded services will get to more students identified as homeless in more LEAs more quickly in order to support them and address the impact of lost instructional time and the other impacts of the pandemic and virtual instruction. The estimated costs and net budget impacts are described below.

Elsewhere, under the *Paperwork Reduction Act of 1995,* we identify and explain burdens specifically associated with information collection requirements.

Need for Regulatory Action and Analysis of Benefits

These final requirements are intended to expedite the award of emergency funds to serve homeless children and youth. As discussed elsewhere in this document, the ARP–HCY program provides vital emergency funding to one of the most vulnerable populations. The Department believes this regulatory action is needed to ensure that SEAs can allocate funds to LEAs in a time-effective manner so that LEAs can begin serving homeless children and youth. Requiring SEAs to make LEA subgrants by formula allows funds to reach more LEAs, and therefore more students experiencing homelessness. These funds will support the work of the designated Homeless Liaison in each LEA, as required by the McKinney-Vento Act, and build capacity in LEAs, which will help to identify greater numbers of students experiencing homelessness and better coordinate services for those students in LEAs receiving funding through this formula. In addition, the funding under ARP is more than seven times greater than the usual appropriation for this program. This onetime emergency appropriation provides a unique opportunity to make funds more widely available than would be possible with the current appropriation of $106.5 million for the Education for Homeless Children and Youth program under the McKinney-Vento Homeless Assistance Act.

The alternative, requiring SEAs to conduct competitions before making awards, would place an additional burden on SEAs and LEAs, increase the time needed to distribute funds, and result in fewer LEAs receiving funds. At the SEA level, a typical competition may take three to six months and requires developing selection criteria, publishing those criteria, providing technical assistance and allowing time for LEAs to develop applications, recruiting and training reviewers, reviewing the applications, and making awards. In addition to the staff time needed to conduct a fair and transparent competition, other expenses may include compensation for reviewers and logistical support for the review process. At the LEA level, costs are incurred in the time needed to develop an application, including identifying and collaborating with partners, and the administrative processes needed to complete the application and obtain approval for submission. Some LEAs, even those with high need, will decline to apply for competitive grants due to these costs and the uncertainty of receiving a grant. In contrast, SEAs already have access to the data and expertise required to run the proposed allocations formula as well as to systems to award the funding to LEAs, as they already administer other Federal formula programs.

We estimate that running a State-level grant competition will take four to six months, and hundreds of staff hours, depending on the number of LEAs in the State who apply for a grant. However, awarding subgrants via a formula would take on average 10–20 hours, with an additional one to two weeks for outreach and technical assistance. At the LEA level, applying for a competitive subgrant could take two weeks to develop and finalize an application; a formula subgrant might take up to 10 hours.

In both scenarios, the reporting burden from the SEA to the Department is small, since the only new information the Department expects to collect is a list of grantees for ARP Homeless I and II disbursements. The Department already collects data from all LEAs in each State for homeless children and youth, whether they receive a McKinney-Vento subgrant or not.

Analysis of Costs

The Department's cost analysis shows that making subgrants by formula is a less costly option overall. As discussed in the previous section, carrying out a competition is a complex, multistep process that occurs over months. The Department estimates that it would take an SEA between 160 to 320 hours to conduct a competition, at an approximate cost of $707,000 to $1,415,000 for 49 SEAs. (SEAs that consist of only one LEA would not need to carry out a competition.) The cost estimates in this section are based on an hourly wage of $45.11, the mean wage estimate for education administrators, other, reported by the U.S. Bureau of Labor Statistics, which is multiplied by two to account for overhead and benefits.

In addition, we estimate that LEAs applying for grants under a competition would need 80 to 100 hours to prepare an application. Because more funding is available under the ARP than under the regular appropriation for the Education for Homeless Children and Youth program, we estimate that more LEAs would apply and receive subgrants than the 4,400 that currently receive subgrants, and the cost estimate assumes that 5,000 LEAs would apply for funds. Using wages as described above, the estimated cost for applications for subgrants would be approximately $36.1 million to $45.1 million, and the total cost for distributing funds via a competition would be approximately $36.8 million to $46.5 million.

In order to distribute funds via formula the Department estimates that SEAs would need 10 to 15 hours to run the formula and distribute funds, and another 40 to 80 hours to conduct outreach to LEAs and help LEAs that would receive less than $5,000 to create consortia with other LEAs. Using wages as described above, the estimated cost for 49 SEAs for these activities would be $221,000 to $420,000. The estimated cost for LEAs to receive subgrants assumes 5 to 10 hours to complete forms and minimal applications for formula funding. The estimate also assumes that approximately 15,000 LEAs would receive funding under the formula, far more than the 5,000 LEAs we estimate would receive funding under a competition for subgrants. The estimated costs to LEAs would be $6.8 million to $13.5 million, and the total

estimated cost for distributing funds via formula would be $7.0 million to $14.0 million. Taking the mean of this range, the estimated cost for distributing funds via formula would be $10.5 million.

Not only does distributing funds via formula present a less costly option, but it also provides several benefits over conducting a competition as discussed in other sections of this document. The main benefits are that formula distribution takes less time and would allow LEAs to receive funds when the school year starts. Furthermore, more LEAs would receive funding, allowing more students to receive services.

Net Budget Impacts

We estimate that the discretionary elements of the final requirements will not have an impact on the Federal budget. The requirements for SEAs and LEAs receiving ARP–HCY funds do not affect the amount of funding available for this program. We anticipate that $799 million in ARP–HCY funds will be disbursed in 2021, and therefore estimate $799 million in transfers in 2021 relative to a pre-statutory baseline.

Accounting Statement

As required by OMB Circular A–4, in the following table, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this regulatory action. This table provides our best estimate of the Federal payments to be made to SEAs under this program as a result of this regulatory action. Expenditures are classified as transfers to those entities.

TABLE—ACCOUNTING STATEMENT CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Costs (in millions)
Annual Costs	$10.5.
Category	**Transfers (in millions)**
Annual Monetized Transfers.	$799.0.
From Whom to Whom	Federal Government to SEAs.

Regulatory Flexibility Act Certification

The Regulatory Flexibility Act does not apply to this rulemaking because there is good cause to waive notice and comment under the Administrative Procedure Act (5 U.S.C. 553).

Clarity of the Regulatory Action

Executive Order 12866 and the Presidential memorandum ''Plain Language in Government Writing'' require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make this regulatory action easier to understand, including answers to questions such as the following:

- Are the requirements in the regulatory action clearly stated?
- Do the regulatory actions contain technical terms or other wording that interferes with their clarity?
- Does the format of the regulatory action (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the regulatory action be easier to understand if we divided them into more (but shorter) sections?
- Could the description of the regulatory action in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the regulatory action easier to understand? If so, how?
- What else could we do to make the regulatory action easier to understand?

To send any comments that concern how the Department could make this regulatory action easier to understand, see the instructions in the **ADDRESSES** section.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*). This helps ensure that the public understands the Department's collection instructions, respondents provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of the law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently-valid OMB control number.

As discussed in the *Need for Regulatory Action and Analysis of Benefits* section of the *Regulatory Impact Statement,* this final requirement that SEAs distribute the ARP Homeless II funds to LEAs by formula rather than competition will create burden hours and costs for both LEAs and SEAs. Below we estimate the annual burden hours and costs for LEAs to complete forms and minimal applications. In addition, the Department is requesting an ARP–HCY plan from each SEA. The burden hours and cost associated with completing and submitting the SEA ARP–HCY plan are estimated below. The cost estimates in this section are based on an hourly wage of $45.11, the mean wage estimate for education administrators, other, reported by the U.S. Bureau of Labor Statistics, which is multiplied by two to account for overhead and benefits, for a total hourly wage estimate of $90.22.

We estimate 7.5 burden hours for each of the approximately 15,000 LEAs to complete forms and minimal applications for formula funding. The total estimated costs to LEAs would be $10,150,000 and the total estimated burden hours would be 112,500.

We estimate that one plan will be received from 52 SEAs. For the time to complete and submit the plan, we estimate that the number of burden hours per response will be 22 hours. The total estimated number of burden hours is 1,144 hours. At $90.22 per hour, the total estimated cost for 52 SEAs to complete and submit the ARP–HCY plan approximately $103,300.

Collectively, we estimate that these new information collection activities will result in a total estimated cost of $10,253,300 and a total estimated burden of 113,644 hours to the public annually.

The Department is requesting an emergency paperwork clearance from OMB under 5 CFR 1320.13 on the data collection activities associated with these final requirements. That request will account for all burden hours and cost discussed within this section. As required by 5 CFR 1320.8(d), the Department is soliciting comments on the information collection. We must receive your comments on the collection activities contained in these final requirements on or before August 9, 2021. Comments related to the information collection activities must be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov* by selecting the Docket ID number ED–2021–OESE–xxx or via postal mail, commercial delivery, or hand delivery by referencing the Docket ID number and the title of the information collection request at the top of your comment. Comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland

Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

Note: The Office of Information and Regulatory Affairs in OMB and the Department review all comments related to the information collection activities posted at *www.regulations.gov*.

COLLECTION OF INFORMATION

Information collection activity	Estimated number responses	Hours per response	Total estimated burden hours	Estimated cost at an hourly rate of $90.22
LEA Completion of Forms and Applications to SEA	15,000	7.5	112,500	$10,150,000
SEA ARP–HCY Plans	52	22	1,144	103,300
Annualized Total	15,052		113,644	10,253,300

Intergovernmental Review

The ARP–HCY program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

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.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021–14705 Filed 7–8–21; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0543; FRL–10024–68–Region 9]

Air Plan Approval; California; El Dorado County Air Quality Management District; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the El Dorado County Air Quality Management District (EDCAQMD) and the South Coast Air Quality Management District (SCAQMD) portions of the California State Implementation Plan (SIP). These revisions concern emissions of volatile organic compounds (VOC) from architectural coatings and a rule that provides definitions for certain terms that are necessary for the implementation of local rules that regulate sources of air pollution. We are approving rules to regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective August 9, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2020–0543. 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 (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3024 or by email at *Lazarus.Arnold@epa.gov.*

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

Table of Contents

I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On March 9, 2021 (86 FR 13514), the EPA proposed to approve the following rules into the California SIP.

Local agency	Rule #	Rule title	Revised/ amended	Submitted
EDCAQMD	215	Architectural Coatings	08/25/2020	09/21/2020
SCAQMD	102	Definition of Terms	01/10/2020	09/16/2020

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. We received three comments during the comment period and each one was supportive of the proposed action.

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving these rules into the California SIP. The August 25, 2020 version of Rule 215 and the January10, 2020 version of Rule 102 will replace the previously approved versions of these rules in the SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the EDCAPCD and the SCAQMD rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 7, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 30, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(207)(i)(B)(*6*), (c)(345)(i)(A)(*3*), and (c)(556) and (557) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(207) * * *

(i) * * *

(B) * * *

(6) Previously approved on July 18, 1996 in paragraph (c)(207)(i)(B)(3) of this section and now deleted with replacement in (c)(557)(i)(A)(1), Rule 215, adopted on September 27, 1994.

* * * * *

(345) * * *

(i) * * *

(A) * * *

(3) Previously approved on January 8, 2007 in paragraph (c)(345)(i)(A)(1) of this section and now deleted with

replacement in (c)(556)(i)(A)(1), Rule 102, adopted on December 3, 2004.

* * * * *

(556) The following rule was submitted on September 16, 2020, by the Governor's designee as an attachment to a letter dated September 16, 2020.

(i) *Incorporation by reference.* (A) South Coast Air Quality Management District.

(*1*) Rule 102, ''Definition of Terms,'' adopted on January 10, 2020.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

(557) The following rule was submitted on September 21, 2020, by the Governor's designee as an attachment to a letter dated September 18, 2020.

(i) *Incorporation by reference.* (A) El Dorado County Air Quality Management District.

(*1*) Rule 215, ''Architectural Coatings,'' adopted on August 25, 2020.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

[FR Doc. 2021–14407 Filed 7–8–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5529–F]

RIN 0938–AU01

Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID–19 Public Health Emergency

Correction

In rule document 2021–09097, appearing on pages 23496 through 23576 in the issue of Monday, May 3, 2021 make the following corrections.

§ 510.400 [Amended]

■ 1. On page 23574, in the second column, in paragraph (b)(4)(ii)(A), on the second line, ''•80%'' should read ''≥80%''.

■ 2. On the same page, in the same column, in the same paragraph, on the third line, ''•300'' should read ''≥300''.

[FR Doc. C1–2021–09097 Filed 7–8–21; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 204, 212, and 252

[Docket DARS–2020–0007]

RIN 0750–AK30

Defense Federal Acquisition Regulation Supplement: Data Collection and Inventory for Services Contracts (DFARS Case 2018–D063)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement to implement a section of the United States Code that requires the collection of data on certain DoD service contracts.

DATES: Effective July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 85 FR 34569 on June 5, 2020, to implement 10 U.S.C. 2330a, as amended by section 812 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328), which requires DoD to establish a data collection system to provide certain management information with regard to an awarded contract or task order that is valued in excess of $3 million and is for the following service acquisition portfolio groups: Logistics management services, equipment-related services, knowledge-based services, or electronics and communications services.

DoD published a prior proposed rule under DFARS Case 2012–D051 in the **Federal Register** at 79 FR 32522 on June 5, 2014, to implement 10 U.S.C. 2330a (section 807 of the NDAA for FY 2008), which required DoD to establish a data collection system to provide certain data on the purchasing of services by DoD and to submit to Congress an annual inventory of services contracts awarded by or on behalf of DoD. The proposed rule for DFARS Case 2012–D051 required contractors to enter the required data into a DoD-unique system, Enterprise Contractor Manpower Reporting Application (ECMRA). In response to public comments received in response to the proposed rule for DFARS Case 2012–D051, DoD made the following changes in the proposed rule for DFARS Case 2018–D063:

- DoD has adopted the service contract reporting process used by other Federal agencies and no longer requires contractor reporting in ECMRA. This change enables DoD to use the Federal Procurement Data System (FPDS) to obtain a majority of the information required by 10 U.S.C. 2330a. FPDS does not provide data on the direct labor hours expended and dollar amounts invoiced for contracted services. Therefore, both the proposed and final rules require applicable contractors to enter the labor hours and dollar amounts in SAM, which is the process used by other Federal agencies, in accordance with Federal Acquisition Regulation (FAR) subpart 4.17.
- To relieve burden and minimize impact for contractors and subcontractors, both the proposed and final rules require contractors to report the total number of hours worked (both contractor and subcontractor) under the contract for the entire fiscal year and does not require a breakdown of those hours by employee type or by subcontractor. The requirement to report subcontractor data is limited to first-tier subcontractors, consistent with the FAR requirement for service contract reporting. The proposed and final rules leave the process for collecting subcontractor data up to the discretion of each contractor; the rules do not prescribe a specific methodology that contractors must use to gather this data on applicable subcontracts, or prescribe a reporting requirement for subcontractors via the flow-down of the contract clause.
- The estimated burdens for respondents and responses published in the proposed rule for DFARS Case 2021–D051 have been updated to reflect the revised requirements of 10 U.S.C. 2330a, as amended.

The following is a summary of the public comments received in response to the proposed rule for DFARS Case 2012–D051:

A. Exemptions

Comment: Several respondents recommended that the rule exempt certain areas including: Research and development projects; architect and engineering services; telecommunications and transmission and internet; and actions using criteria similar to the Service Contract Labor Standards exemptions in FAR 22.1003–4(d)(1).

Response: The proposed rule for DFARS Case 2018–D063 implements 10 U.S.C. 2330a, as amended by section 812 of the NDAA for FY 2017, which

requires reporting for only four service acquisition portfolio groups: Logistics management services, equipment related services, knowledge-based services, and electronics and communications services. No further exemptions are available under the law.

Comment: Several respondents recommended that contracted services that meet the definition of commercial items be exempt from ECMRA reporting.

Response: An exception for services that meet the definition of a commercial item would exclude significant sums expended by DoD on commercial service acquisitions intended to be covered by the law. The intent of the statute is to enhance DoD's ability to manage the total force, inclusive of military, civilian, and contractor personnel. Specifically, section 2330a requires the military departments and defense agencies to ensure that the inventory of contracts for services required by the statute is used to inform strategic workforce planning decisions under 10 U.S.C. 129a, develop budget justification materials for services in accordance with 10 U.S.C. 235, and ensure services contracts are not for the performance of inherently governmental functions. Therefore, services meeting the definition of a commercial item are not exempt from the reporting requirement.

Comment: Several respondents recommended that firm fixed-price service contracts be exempt from the ECMRA reporting requirement, because these contracts acquire services in their entirety, not as individuals (full-time equivalents).

Response: In accordance with paragraph (b) of 10 U.S.C. 2330a, the data required to be collected under the statute includes service contracts and orders that contain firm fixed-prices for the specific tasks to be performed. Therefore, firm fixed-price contracts for the applicable services are not exempt under the proposed rule for DFARS Case 2018–D063.

Comment: One respondent recommended that the rule exempt DoD intelligence community agency contracts, because the existing exemption for ''classified services'' is not sufficient to cover the exempt contracts entered into by DoD intelligence community agencies.

Response: The statute does not provide for exemptions to the reporting requirement; therefore, the proposed rule for DFARS Case 2012–D051 does not provide for exemptions, in order to comply with the law.

Comment: One respondent recommended that, due to the difficulty in tracking labor for service contracts where contractor employees may spend only small fractions of their time servicing the Government contract (such as refuse collection and software as a service), the rule should be changed to exempt such contracts by using the criteria similar to the Service Contract Labor Standards exemptions (see FAR 22.1003–4(d)(1)).

Response: Title 10 U.S.C. 2330a, as amended by section 812 of the NDAA for FY 2017, now limits data collection to four service acquisition portfolio groups: Logistics management services, equipment related services, knowledge-based services, and electronics and communications services. Under the proposed rule for DFARS Case 2018–D063, only service contracts with a total estimated value exceeding $3 million that are for services in one of the four portfolio groups must be reported in SAM.

Comment: One respondent questioned whether Congress intended DoD to report contracts for services that are integrally related to supplies, or contracts where the services are a relatively small dollar value in relation to the supplies.

Response: Title 10 U.S.C. 2330a requires the collection of data on ''each purchase of services by a military department or Defense Agency'' that meets a certain dollar threshold and is for certain services. The proposed rule for DFARS Case 2018–D063 clarifies that the requirement applies to contracts or orders that have a total estimated value, including options, exceeding $3 million and are for services in one of the four service acquisition portfolio groups.

B. Expansion of Reporting Requirement

Comment: Two respondents suggested that the ECMRA reporting requirement be extended to contracts for services valued at or below the simplified acquisition threshold (SAT). Doing so would be consistent with the congressional intent in 10 U.S.C. 2330a for DoD to provide a total inventory of contracted services.

Response: Title 10 U.S.C. 2330a(a), as amended by section 812 of the NDAA for FY 2017, now only requires the collection of data on service contracts, under certain portfolio groups, that exceed $3 million. The proposed rule for DFARS Case 2018–D063 implements the statutory threshold. Applying the rule to service contracts below $3 million is not necessary to implement the statute and would impose an unnecessary burden on the public and DoD.

Comment: One respondent suggested that the final rule clarify that services provided ancillary to a lease or rental contract (such as auto repair and maintenance services incidental to a vehicle lease) are subject to ECMRA reporting requirement. The respondent also recommended that the final rule clarify that the ECMRA reporting requirements apply to contracts for destruction, demolition, and removal.

Response: Title 10 U.S.C. 2330a(a), as amended by section 812 of the NDAA for FY 2017, specifies that the service acquisition portfolio group for equipment related services is included in the required reporting group. It is expected that contracts for equipment-related services with a total estimated value, including options, exceeding $3 million will be reported in SAM.

C. Duplicative of Existing Systems

Comment: Two respondents indicated that the rule is duplicative of the existing FAR rule on service contract reporting that applies to civilian agencies (see FAR subpart 4.17). Respondents stated that there should not be two parallel systems, one for civilian agencies and another for defense agencies, because this situation causes confusion and compliance problems within industry.

Response: FAR subpart 4.17 does not apply to DoD. The proposed rule for DFARS Case 2018–D063 enables DoD to fulfill its obligation under 10 U.S.C. 2330a. Since publication of the proposed rule under DFARS Case 2012–D051, DoD has adopted the use of FPDS to collect a majority of the required data, in an effort to standardize the reporting process for contractors across the Federal Government.

Comment: Several respondents suggested that the ECMRA system is duplicative of other Government systems, such as FPDS, which can also be used to estimate the data provided in the annual inventory of contracts for services.

Response: DoD has adopted the service contract reporting process used by other Federal agencies and no longer requires contractor reporting in ECMRA. This rule will enable DoD to use FPDS to obtain a majority of the information required by 10 U.S.C. 2330a. FPDS does not provide data on the direct labor hours expended and dollar amounts invoiced for contracted services. Therefore, the proposed rule for DFARS Case 2018–D063 requires applicable contractors to enter the labor hours and dollar amounts in SAM, which is the process used by other Federal agencies, in accordance with FAR subpart 4.17.

Comment: Two respondents suggested that the separate instances of ECMRA (Army, Navy, Air Force, and other DoD

agencies) be combined into one DoD-wide ECMRA system.

Response: The use of ECMRA is no longer necessary. The proposed rule for DFARS Case 2018–D063 requires contractors to enter information in SAM.

Comment: Two respondents suggested that the rule is duplicative of existing DoD reporting requirements, such as: (1) The Army's contractor manpower reporting requirement; and (2) the Secretary of Defense Memorandum entitled ''Enterprise-wide Contractor Manpower Reporting Application,'' dated November 2012, that requires all new contracts for services to include a contract line item for contractor manpower reporting and a requirement in the performance work statement for contractor manpower reporting.

Response: This rule will replace, not duplicate, the existing Army contract manpower reporting requirement and the requirements in the November 2012 Memorandum from the Under Secretary of Defense for Acquisition, Technology, and Logistics and the Acting Principal Deputy Under Secretary of Defense for Personnel and Readiness.

Comment: Two respondents suggested that the rule exceeds the scope of congressional intent, because DoD is already using its internal records and systems to achieve the statutory objective of the inventory of contracts for services.

Response: The rule does not exceed the scope of congressional intent, because existing systems and reports do not fully capture all of the data required by 10 U.S.C. 2330a.

D. Flow Down to Subcontracts

Comment: Two respondents suggested that the requirement for subcontract reporting be changed. One respondent suggested that the prime contractor be required only to flow down the clause to subcontractors and relieved of the responsibility of reporting for subcontractors. The other respondent suggested that subcontractor data not be reported at all, as this is inconsistent with commercial practice.

Response: The proposed rule for DFARS Case 2018–D063 does not contain a requirement to flow down a clause. Instead, the proposed rule requires contractors to include its subcontractor labor hours in the total number of labor hours the contractor reports annually to SAM. The proposed rule leaves the process for collecting subcontractor data up to the discretion of each contractor.

E. Need for Additional Resources

Comment: One respondent suggested that more resources be provided to the Office of the Under Secretary of Defense for Personnel and Readiness workforce that administers and coordinates the inventory of contracts for services.

Response: This suggestion is beyond the scope of the rule.

F. ECMRA Process

Comment: One respondent noted that the ECMRA interface for the Fourth Estate (other DoD agencies and field activities) is not yet fully operational, in contrast to what is stated in the proposed rule. For example, there is no operational help desk support for Fourth Estate activities. The respondent suggests that the final rule should be delayed until ECMRA is consolidated into a common portal for all DoD agencies, or until the ECMRA instance for Fourth Estate activities is fully resourced.

Response: The use of ECMRA is no longer necessary. The proposed rule for DFARS Case 2018–D063 requires contractors to enter information in SAM.

Comment: One respondent questioned how the Government validates data provided by contractors in ECMRA. The respondent suggested that ECMRA be linked to Wide Area WorkFlow and that the contracting officer or the contracting officer's representative be allowed to inspect payroll data in order to validate contractor data entered into ECMRA.

Response: Agencies are responsible for ensuring the contractor submits information in SAM that is reasonable and consistent with available contract information. Agencies may use any contract data available, as appropriate and necessary, to meet this responsibility.

Comment: One respondent suggested that the rule be clearer about how the ECMRA will protect nonpublic data, such as direct labor hours and cost data.

Response: The use of ECMRA is no longer necessary.

Comment: One respondent requested clarification on the procedures to follow when the services under one contract support two or more DoD services or agencies.

Response: The proposed rule for DFARS Case 2018–D063 requires contractors to enter information in SAM, which is a single system able to collect all requisite data under this rule.

Comment: One respondent suggested that ECMRA should have a built-in capability for an overall point of contact at each agency level who can gather and manage the ECMRA information and that data be gathered at a centralized location.

Response: The use of ECMRA is no longer necessary. The proposed rule for DFARS Case 2018–D063 requires contractors to enter information in SAM, which is a Governmentwide system.

Comment: One respondent noted that it is unduly restrictive to allow only one contractor user per contract to view the data for that contract in ECMRA.

Response: The use of ECMRA is no longer necessary. The proposed rule for DFARS case 2018–D063 requires contractors to enter information in SAM.

Comment: One respondent suggested that the rule should clarify the contractor's responsibilities in the event that the Government-populated information in ECMRA is incorrect.

Response: The use of ECMRA is no longer necessary. The proposed rule for DFARS Case 2018–D063 requires contractors to enter information in SAM. Contractors may contact the SAM Helpdesk or the contracting officer in the event that data needs to be updated in SAM.

Comment: One respondent suggested that the requiring activity, and not the contracting officer, be responsible for verifying the contractor's ECMRA compliance is documented.

Response: In accordance with FAR 1.602–2, the contracting officer is responsible for ensuring compliance with the terms of the contract.

Comment: A respondent suggested that a DD Form 1423, Contract Data Requirements List, be included as a requirement in the rule.

Response: The proposed DFARS clauses convey the requirement for contractor reporting to SAM; therefore, a DD Form 1423 is not necessary.

G. Proposed Clause Changes

Comment: One respondent requested clarification regarding the prescription for the clause at DFARS 252.237–70XX with regard to indefinite-delivery, indefinite-quantity contracts. The respondent asked whether the clause must be included only if the expected dollar value of the individual task or delivery orders will exceed the SAT or if the total dollar value of all the task or delivery orders issued under the contract will exceed the SAT.

Response: The rule requires information reporting on each task order that meets the criteria and threshold for service contract reporting. The proposed rule for DFARS Case 2018–D063 does not require reporting at the contract level for indefinite-delivery contracts. The rule proposes a basic clause that

applies to solicitations, contracts (other than indefinite-delivery contracts), and task orders awarded under non-DoD indefinite-delivery contracts; and an alternate clause that applies to DoD issued solicitations and contracts for indefinite-delivery type contracts. The basic clause and the alternate clause implement the reporting requirement for contracts and/or task orders that have a total estimated value, including options, exceeding $3 million and are for services in the four specified service acquisition portfolio groups. The basic clause advises contractors to report on the effort performed under the contract or the task order awarded under a non-DoD contract. The alternate clause advises the contractor to report on the effort performed under each task order awarded under a DoD indefinite-delivery contract that meets the criteria and threshold for service contract reporting.

Comment: One respondent suggested that the rule include a link to the product service code (PSC) manual available at *www.acquisition.gov,* to aid contracting personnel in determining the types of services to which the proposed rule applies or does not apply.

Response: The applicable PSCs will be identified in the DFARS Procedures, Guidance, and Information upon publication of the final rule.

Comment: One respondent suggested that the rule require the contracting officer to prepare a determination designating specifically the services to which the ECMRA reporting requirement would apply.

Response: It is not necessary for the contracting officer to prepare such a determination or provide further clarification to the contractor. The proposed rule for DFARS Case 2018–D063 only applies the requirement to report in SAM, via the DFARS clause, to those contracts and orders that meet the thresholds and criteria for service contract reporting, as expressed in 10 U.S.C. 2330a.

H. Definition Clarification

Comment: One respondent noted that many terms, including ''direct labor hours'' and ''cost data,'' are not defined in the proposed rule.

Response: This proposed rule only uses the term ''direct labor hours,'' which is defined in FAR 2.101.

Comment: Two respondents recommended that the term ''services'' be better defined for the purposes of informing both the Government and contractor when the proposed rule for DFARS Case 2012–D051 applies and when the contractor is responsible for entering data into ECMRA.

Response: The proposed rule for DFARS Case 2018–D063 only applies the requirement to report in SAM, via the DFARS clause, to those contracts and orders that meet or are expected to meet the thresholds and criteria for service contract reporting, as expressed in 10 U.S.C. 2330a. When awarded a contract, or task order placed under a non-DoD contract, this rule proposes a basic clause to notify contractors of the requirement to report in SAM on the effort performed under the award. When awarded an indefinite-delivery contract under which orders will be placed that may meet the thresholds and criteria for service contract reporting, this rule proposes an alternate clause to notify contractors of the requirement to report in SAM on the effort performed for a task order issued under the contract that meets the service contract reporting thresholds and criteria.

I. Major Rule

Comment: One respondent suggested that the Government reconsider whether this is a major rule. Title 5 U.S.C. 804 defines a major rule as one which the Office of Management and Budget (OMB) determines will cause a major increase in costs or prices for individual industries, or have a significant adverse effect on competition, employment, investment, productivity, or innovation. This rule imposes new reporting requirements, particularly for commercial item contractors that provide professional services and supplies. These contractors would not have been previously subject to the type of manpower reporting required by this rule. For small businesses, the need to build compliant procedures and automated systems could be a barrier to participating in the federal market. This is particularly the case when the cumulative effect of multiple and duplicative data reporting requirements is considered. The ultimate result over time will be a decrease in competition and innovation in the Federal market.

Response: This rule is not a major rule in that it does not have a significant impact on competition, employment, investment, productivity, innovation, or on the ability of U.S. enterprises to compete with foreign enterprises. Similar reporting requirements for civilian agencies have appeared in FAR subpart 4.17 since 2014, so many contractors already have experience with this type of reporting requirement. The scope of this rule has been decreased, because 10 U.S.C. 2330a, as amended by section 812 of the NDAA for FY 2017, limits data collection to four service acquisition portfolios and applies only to contracts and task orders exceeding $3 million in total estimated value, including options.

J. Initial Regulatory Flexibility Analysis

Comment: Two respondents stated that the proposed reporting system did not have a goal of minimizing the burden to small business and that the constant flow of new regulations to businesses have little regard for the benefit to the Government or burden on businesses.

Response: The burden applied to small businesses is the minimum consistent with applicable laws, Executive orders, regulations, and prudent business practices. The information collection requirement has been narrowly tailored to maximize the use of existing records already maintained by contractors and by the Government. To further minimize the impact, DoD is adopting the existing system and process used by the rest of the Government to obtain the requisite information from contractors, which maintains a familiar and consistent reporting requirement for contractors; and the information is collected electronically, help-desk support and user guides are available for SAM, and reporting requirements will be limited to a small number of data elements to facilitate ease of reporting and reduce contractor burden. In addition, the NDAA for FY 2017 raised the threshold for reporting to $3 million from the SAT and limited the data reporting to four service acquisition portfolio groups.

K. Paperwork Reduction Act

1. Government Systems Already in Place

Comment: Two respondents stated that the Government has systems in place for collecting the required data and the rule would require duplicative contractor reporting that is not necessary for compliance. Two respondents noted that there will be two rules, one for DoD and the other non-DoD, which could potentially apply under a single contract vehicle and that determining which set of rules apply will be burdensome.

Response: The rule will not require duplicative reporting by contractors. The DoD and non-DoD reporting requirements are based on separate statutes. Further, the information collection requirement associated with this DFARS Case 2018–D063, once cleared by OMB, will supersede the reporting requirements approved under OMB Control Number 0704–0491, entitled ''DoD Inventory of Contracts for Services Compliance.'' Contracts awarded by DoD, or on behalf of DoD,

will contain the proposed DFARS clauses.

2. Paperwork Reduction Act Constraints

Comment: One respondent stated that the rule conflicts with Paperwork Reduction Act constraints on rulemaking, namely that the rule must: (1) Be necessary for the proper performance of the agency; (2) not be duplicative of information otherwise reasonably accessible to the agency; and (3) reduce, to the extent practicable and appropriate, the burden on persons who shall provide information to or for the agency.

Response: The rule complies with the Paperwork Reduction Act. The information collection is necessary in order for DoD to meet the requirement of 10 U.S.C. 2330a, as amended, to collect certain service contract data and report annually to Congress. The rule is not duplicative of information otherwise reasonably accessible to DoD. DoD systems do not currently collect all of the data elements required by the statute.

The information collection requirement has been narrowly tailored to minimize the impact of reporting and maximize the use of existing records already maintained by contractors and by the Government. To minimize the impact, the information will be collected electronically, help-desk support will be provided to users, and reporting requirements will be limited to a small number of data elements.

3. Burden Estimates

Comment: Two respondents commented that the rule underestimates the number of contractors that will be impacted. One respondent indicated that the total estimated number of respondents of 13,269, including 7,962 for small businesses, seems low, since the GSA Schedules alone have 20,000 contractors and 80% of the contractors are small businesses. One respondent stated that the estimate for the total number of annual responses of approximately 54,000 appears low. In addition, several respondents commented that the estimate of an average of 1.4 hours per response is too low, citing reasons such as: (1) The billions of dollars in services for which DoD contracts for annually and the corresponding volume of data required to be entered, (2) the limitation of the ECMRA bulk upload capability, or (3) the impact on response time resulting from the flow down of the reporting requirement to subcontractors. One respondent stated that the burden is disproportionally high for small businesses that are less likely to have the necessary internal infrastructure.

Response: The estimated burdens for respondents and responses published in the previously proposed rule have been updated to reflect the revised requirements of 10 U.S.C. 2330a, as amended.

As a result, this final rule amends the DFARS to require contractors to annually report certain data on applicable contracts in order to meet the data requirements of the statute and DoD's total workforce management efforts. Three respondents submitted public comments in response to this second proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

No significant changes were made to the rule as a result of public comments. Minor changes were made to clarify the intent of the rule in regard to the requirement to report subcontract data. Public comments requested clarification on whether the rule required contractors to report direct labor hours and costs for all subcontracts that support the contract or just those subcontracts awarded to directly perform services under the contract, otherwise referred to as ''first-tier subcontracts'' under the similar service contract inventory reporting requirements at Federal Acquisition Regulation (FAR) 4.17. The intent of the rule is to require contractors to report the direct labor hours only for subcontracts the contractor directly awarded for the purpose of acquiring services for performance of the prime contract, similar to the subcontract reporting requirement at FAR 4.17. As a result, the term ''first-tier'' was added as a modifier to the definition of ''subcontract'' and a definition of ''first-tier subcontract'' was added to section 204.1701 and DFARS clause 252.204–7023, Reporting Requirements for Contracted Services, and its alternate I.

B. Analysis of Public Comments

A discussion of the comments is provided as follows:

a. General Support

Comment: Two respondents expressed general support for the rule.

Response: DoD acknowledges support for the rule.

b. Exemptions to Rule

Comment: Two respondents recommended that commercial service contracts be exempt from the rule, as companies providing commercial services may not have a system to track labor hours by contract and/or by subcontractor and may need to implement a new system to comply with the rule. Alternately, a respondent recommended that specific contracts or certain types of commercial contracts be exempt from the reporting requirements for the rule.

Response: The statute requires DoD to collect data on specific service purchases in excess of $3 million, regardless of contract type, and does not provide for exemptions to the reporting requirement. As a result, the rule applies to all contracts that meet the criteria at 10 U.S.C. 2330a(a) and does not provide for exemptions.

c. Usefulness of Data

Comment: A respondent advised that the rule weakens the utility of service contract inventories by limiting them to staff augmentation contracts and contracts closely associated with inherently governmental functions, and preventing the adoption of the Enterprise-wide Contractor Manpower Reporting Application (ECMRA).

Response: The rule implements the statute and supports DoD total workforce management efforts by requiring reporting on contracts valued in excess of $3 million for logistics management services, equipment-related services, knowledge-based services, or electronics and communications services. The rule does not further limit the reporting requirement to only those contracts that are also staff augmentation contracts or contracts for services closely associated with inherently governmental functions.

The rule also incorporates the policy of Secretary of Defense Memorandum, *Revised Department of Defense Contractor Manpower Reporting Initiative,* dated October 16, 2019, jointly signed by the Under Secretary of Defense (USD) for Acquisition and Sustainment and Acting USD for Personnel and Readiness. The memo requires reporting of manpower data relating to the performance of services be done in the System for Award Management (SAM), instead of ECMRA, in order to be consistent with the existing service contract reporting requirements of the FAR.

Comment: A respondent expressed concern that the rule only requires reporting on the aggregate labor hours performed under the contract annually

and, because of this, DoD will not have the detailed information it needs to determine whether contractors are performing inherently governmental functions.

Response: The rule requires the collection of data that supplements information already available to DoD. The rule assists in the evaluation of DoD's workforce mix and the extent to which the Department's needs are being met through contracted support. It is not necessary to distinguish between the contractor and subcontractor labor hours performed under a contract in order to meet the requirements of the statute or support DoD's total workforce management efforts.

Comment: A respondent expressed concern that the rule's collection of labor data cannot be meaningfully used by officials, as the annual reporting cycle will not produce the timely, relevant data needed to inform decision making.

Response: The rule implements the reporting cycle required by 10 U.S.C. 2330a. The statute requires DoD, by the end of the third quarter of each fiscal year, to prepare an annual inventory of the activities performed during the preceding fiscal year pursuant to staff augmentation contracts and contracts closely associated with inherently governmental functions. To support this requirement, the rule requires contractors to input contract data for the preceding fiscal year in SAM no later than October 31 of each fiscal year. The rule's October 31 deadline facilitates DoD's compilation and submission of the annual inventory and summary before the third quarter of each fiscal year, as required by 10 U.S.C. 2330a.

d. Difficulties Reporting Direct Labor Hour Data

Comment: Two respondents advised that the reporting requirement of the rule may be difficult to meet, because many commercial services are offered at a fixed price and are not broken down into direct labor hours, and subcontractors may consider the data sensitive or proprietary and be hesitant to provide it to contractors. A respondent advised that, as a result of these issues, the rule may create cost and competition implications for the supply chain because contractors may have to create and price contractual requirements to obtain the information from their subcontractors, and the number of available vendors may be restricted if they choose not to provide the data required by the rule.

As an alternative solution, two respondents recommended that the rule limit the collection of data to the list explicitly identified at 10 U.S.C. 2330a(b). Respondents suggested that DoD could apply the methodology used to determine military or civilian full-time equivalents to the data at 10 U.S.C. 2330a(b) in order to fulfill the inventory summary required by 10 U.S.C. 2330a(c).

Response: The statute requires that ''the number of contractor employees, expressed as full-time equivalents for direct labor, using direct labor hours and associated cost data collected from contractors'' be provided for each contract included in the annual inventory. This information is not included in the list of data at 10 U.S.C. 2330a(b).

While the Federal Procurement Data System provides DoD with a majority of the requisite data, DoD cannot meet all of the statutory data requirements of the inventory summary, or support the needs of DoD's total workforce management efforts, using only the data listed at 10 U.S.C. 2330a(b). Therefore, this rule requires contractors to provide direct labor hour and cost data to implement the statute and support DoD workforce planning and analysis.

To relieve burden and minimize impact for contractors and subcontractors, the rule requires contractors to report the total number of hours (both contractor and subcontractor) worked under the contract for the entire fiscal year and does not require a breakdown of those hours by employee type or by subcontractor.

e. Reporting of Subcontractor Data

Comment: A respondent recommended that the requirement to report subcontractor data be limited to first-tier subcontractors, which is consistent with the current FAR requirements for civilian agencies.

Response: Concur. To reduce burden on and maintain consistency for contractors, DoD intends for the reporting requirements and procedures of this rule to be as similar as possible to the existing service contract reporting requirements of the FAR. The intent of the rule is for contractors to report the total number of direct labor hours expended in performing the contracted services during the preceding fiscal year. The total number of hours reported to SAM should represent a combined total of the number of direct labor hours the contractor itself expended performing the contracted services, and the total number of direct labor hours any of the contractor's subcontractors expended performing the contracted services. To clarify this intent, the rule is amended to replace the term ''subcontract'' with ''first-tier subcontract,'' based on the definition at FAR 4.1701.

Comment: A respondent recommended the rule be revised to specifically authorize contractors to rely on the direct labor hour data received from subcontractors when reporting total labor hours annually in SAM.

Response: The rule simply requires the reporting of the direct labor hours expended on the contracted service for the preceding fiscal year. The rule does not prescribe or suggest a specific methodology that contractors must use to gather this data on its applicable subcontracts, or prescribe a reporting requirement for subcontractors via the flow-down of the contract clause. Therefore, an amendment to the rule to authorize a specific methodology for gathering the data is not necessary.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not apply the requirements of 10 U.S.C. 2330a, as amended by section 812 of the NDAA for FY 2017, to contracts at or below the simplified acquisition threshold (SAT) or for commercially available off-the-shelf items (COTS) items, but does apply the rule to contracts for the acquisition of commercial items.

A. Background

Section 812 of the NDAA for FY 2017 is silent on applicability to contracts and subcontracts in amounts no greater than the SAT or for the acquisition of commercial items. 10 U.S.C. 2330a(a), as amended by section 812 of the NDAA for FY 2017, only requires the collection of data on service contracts, under certain portfolio groups, that exceed $3 million, which effectively precludes application to acquisitions under the SAT. Also, the statute does not provide for civil or criminal penalties. Therefore, the statute does not apply to contracts or subcontracts in amounts not greater than the SAT or to the acquisition of commercial items unless the Principal Director, Defense Pricing and Contracting, makes a written determination as provided in 41 U.S.C. 1905 and 10 U.S.C. 2375.

B. Applicability To Contracts for the Acquisition of Commercial Items, Excluding COTS Items

10 U.S.C. 2375 exempts contracts and subcontracts for the acquisition of commercial items, including COTS items, from provisions of law enacted after October 13, 1994, that, as

determined by the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)), set forth policies, procedures, requirements, or restrictions for the acquisition of property or services unless—

- The provision of law—
  - Provides for criminal or civil penalties;
  - Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 2533a or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 2533b;
  - Specifically refers to 10 U.S.C. 2375 and states that it shall apply to contracts and subcontracts for the acquisition of commercial items (including COTS items); or
  - USD(A&S) determines in writing that it would not be in the best interest of the Government to exempt contracts or subcontracts for the acquisition of commercial items from the applicability of the provision.

This authority has been delegated to the Principal Director, Defense Pricing and Contracting.

Consistent with 10 U.S.C. 2375, DoD has determined that it is in the best interest of the United States to apply the requirements of 10 U.S.C. 2330a to the acquisition of commercials items, excluding COTS items. The intent of the statute is to enhance DoD's ability to manage the total force, inclusive of military, civilian, and contractor personnel. Specifically, section 2330a, as amended, requires the military departments and defense agencies to ensure that the inventory of contracts for services required by the statute is used to inform strategic workforce planning decisions under 10 U.S.C. 129a and develop budget justification materials for services in accordance with 10 U.S.C. 235. An exception for services that meet the definition of a commercial item would exclude significant sums expended by DoD on contracted services intended to be covered by the law, thereby undermining the overarching public policy purpose of the law. Therefore, this rule will apply to the acquisition of commercial items, excluding COTS items.

IV. Executive Orders 12866 and 13563

Executive orders (E.O.s) 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, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804(2).

VI. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The objective of this rule is to implement 10 U.S.C. 2330a, as modified by section 812 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328), which requires DoD to establish a data collection system that provides management information on each purchase of services by a military department or defense agency in excess of $3 million for the following service acquisition portfolio groups: Logistics management services; equipment-related services; knowledge-based services; and electronics and communications services.

As a result, DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to require contractors to annually report certain data on applicable contracts in order to meet the data requirements of the statute and DoD's total workforce management efforts. No public comments were received in response to the initial regulatory flexibility analysis.

Based on data from the Federal Procurement Data System for FY 2016 through 2018, DoD awards annually an average of 4,386 service contracts and orders to 1,934 unique entities that have an estimated value greater than $3 million and are within the four portfolio groups outlined in the rule. Of the 4,386 contracts and orders awarded annually, approximately 2,059 (47 percent) are made to 1,227 (63 percent) unique small entities.

This rule requires all contractors that are awarded a contract or order in excess of $3 million for services in any of the four service acquisition portfolio groups to report contract data in the System for Award Management (SAM). The contractor is required to report the total amount invoiced for services performed during the preceding fiscal year and the number of direct labor hours, including first-tier subcontractor hours, expended on services performed during the preceding fiscal year. The Government estimates that a journeyman level contractor employee with basic knowledge of the contract would be required to enter the data. The contractor employee may also need to gather additional billing information from the organization in order to complete the data input in SAM.

While this rule does not impose a significant economic impact on small entities, DoD has taken steps to minimize the impact of the rule on both small and large entities. Specifically, DoD now requires reporting under the rule to be done in SAM, instead of the Enterprise-wide Contractor Manpower Reporting Application (ECMRA). This change permits contractors to report fewer data elements under the rule and implements a data collection system that is familiar to contractors under the existing service contract reporting requirements of the Federal Acquisition Regulation.

VII. Paperwork Reduction Act

This rule contains information collection requirements that have been approved by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). This information collection requirement has been assigned OMB Control Number 0704–0519, entitled ''Defense Federal Acquisition Supplement (DFARS); Subpart 204.17, Service Contracts Inventory, and Associated Clause.''

List of Subjects in 48 CFR Parts 204, 212, and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 204, 212, and 252 are amended as follows:

■ 1. The authority citation for parts 204, 212, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 204—ADMINISTRATION AND INFORMATION MATTERS

■ 2. Add subpart 204.17, consisting of 204.1700, 204.1701, 204.1703, and 204.1705, to read as follows:

SUBPART 204.17—SERVICE CONTRACTS INVENTORY

Sec.
204.1700 Scope of subpart.
204.1701 Definitions.
204.1703 Reporting Requirements.
204.1705 Contract clauses.

SUBPART 204.17—SERVICE CONTRACTS INVENTORY

204.1700 Scope of subpart.

This subpart prescribes the requirement to report certain contracted services in accordance with 10 U.S.C. 2330a.

204.1701 Definitions.

As used in this subpart—

First-tier subcontract means a subcontract awarded directly by the contractor for the purpose of acquiring services for performance of a prime contract. It does not include the contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies or services that benefit multiple contracts and/or the costs of which are normally applied to a contractor's general and administrative expenses or indirect costs.

204.1703 Reporting requirements.

(a) *Thresholds.* Service contractor reporting of information is required in the System for Award Management (SAM) when a contract or order—

(i) Has a total estimated value, including options, that exceeds $3 million; and

(ii) Is for services in the following service acquisition portfolio groups (see PGI 204.1703 for a list of applicable product and service codes):

(A) Logistics management services.

(B) Equipment-related services.

(C) Knowledge-based services.

(D) Electronics and communications services.

(b) *Agency reporting responsibilities.* In the event the agency believes that revisions to the contractor-reported information are warranted, the agency shall notify the contractor.

(S–70) *Contractor reporting.* (1) The basic and the alternate of the clause at 252.204–7023, Reporting Requirements for Contracted Services, require contractors to report annually, by October 31, on the services performed under the contract or order, including any first-tier subcontracts, during the preceding Government fiscal year.

(2) For indefinite-delivery contracts, basic ordering agreements, and blanket purchase agreements—

(i) Contractor reporting is required for each order issued under the contract or agreement that meets the requirements of paragraph (a) of this section; and

(ii) Service contract reporting is not required for the basic contract or agreement.

204.1705 Contract clauses.

(a)(i) Use the basic or the alternate of the clause 252.204–7023, Reporting Requirements for Contracted Services, in solicitations, contracts, agreements, and orders, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, that—

(A) Have a total estimated value, including options, that exceeds $3 million; and

(B) Are for services in the following service acquisition portfolio groups:

(*1*) Logistics management services.

(*2*) Equipment-related services.

(*3*) Knowledge-based services.

(*4*) Electronics and communications services.

(ii) Use the basic clause in solicitations and contracts, except solicitations and resultant awards of indefinite-delivery contracts, and orders placed under non-DoD contracts that meet the criteria in paragraph (a)(i) of this section.

(iii) Use the alternate I clause in solicitations and resultant awards of indefinite-delivery contracts, basic ordering agreements, and blanket purchase agreements, when one or more of the orders under the contract or agreement are expected to meet the criteria in paragraph (a)(i) of this section.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 3. Amend section 212.301 by adding paragraph (f)(ii)(N) to read as follows:

* * * * *

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(ii) * * *

(N) Use the clause at 252.204–7023, Reporting Requirements for Contracted Services, to comply with 10 U.S.C. 2330a.

(*1*) Use the basic clause as prescribed in 204.1705(a)(i) and (ii).

(*2*) Use the alternate I clause as prescribed in 204.1705(a)(i) and (iii).

* * * * *

Part 252—Solicitation Provisions and Contract Clauses

■ 4. Add section 252.204–7023 to read as follows:

252.204–7023 Reporting Requirements for Contracted Services.

Basic. As prescribed in 204.1705(a)(i) and (ii), use the following clause:

Reporting Requirements for Contracted Services—Basic (Jul 2021)

(a) *Definition.* As used in this clause—

First-tier subcontract means a subcontract awarded directly by the contractor for the purpose of acquiring services for performance of a prime contract. It does not include the contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies or services that benefit multiple contracts and/or the costs of which are normally applied to a contractor's general and administrative expenses or indirect costs.

(b) The Contractor shall report annually, by October 31, at *https://www.sam.gov,* on the services performed under this contract or order, including any first-tier subcontracts, during the preceding Government fiscal year (October 1–September 30).

(c) The Contractor shall report the following information for the contract or order:

(1) The total dollar amount invoiced for services performed during the preceding Government fiscal year under the contract or order.

(2) The number of Contractor direct labor hours, to include first-tier subcontractor direct labor hours, as applicable, expended on the services performed under the contract or order during the previous Government fiscal year.

(d) The Government will review the Contractor's reported information for reasonableness and consistency with available contract information. In the event the Government believes that revisions to the Contractor's reported information are warranted, the Government will notify the Contractor. Upon notification, the Contractor shall revise the reported information or provide the Government with a supporting rationale for the information.

(End of clause)

Alternate I. As prescribed in 204.1705 (a)(i) and (iii), use the following clause, which substitutes ''contract or agreement for each order'' in lieu of ''contract or order'' in paragraph (b) and ''order'' in lieu of ''contract or order'' in paragraphs (c) and (c)(1) and (2), and identifies the dollar threshold and service acquisition portfolio groups for which orders under the contract or agreement require service contract reporting.

Reporting Requirements for Contracted Services—Alternate I (Jul 2021)

(a) *Definition.* As used in this clause—

First-tier subcontract means a subcontract awarded directly by the contractor for the purpose of acquiring services for performance of a prime contract. It does not include the contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies or services that benefit multiple contracts and/or the costs of which are normally applied to a contractor's general and administrative expenses or indirect costs.

(b) The contractor shall report annually, by October 31, at *https://www.sam.gov,* on services performed during the preceding Government fiscal year (October 1–September 30) under this contract or agreement for each order, including any first-tier subcontract, which exceeds $3 million for services in the following service acquisition portfolio groups:

(1) Logistics management services.

(2) Equipment-related services.

(3) Knowledge-based services.

(4) Electronics and communications services.

(c) The Contractor shall report the following information for the order:

(1) The total dollar amount invoiced for services performed during the preceding Government fiscal year under the order.

(2) The number of Contractor direct labor hours, to include first-tier subcontractor direct labor hours, as applicable, expended on the services performed under the order during the previous Government fiscal year.

(d) The Government will review the Contractor's reported information for reasonableness and consistency with available contract information. In the event the Government believes that revisions to the Contractor's reported information are warranted, the Government will notify the Contractor. Upon notification, the Contractor shall revise the reported information or provide the Government with a supporting rationale for the information.

(End of clause)

[FR Doc. 2021–14429 Filed 7–8–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No: 210702–0144; RTID 0648–XW035]

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications; 2021–2022 Annual Specifications and Management Measures for Pacific Sardine

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

ACTION: Final rule.

SUMMARY: NMFS is implementing annual harvest specifications and management measures for the northern subpopulation of Pacific sardine (hereafter, Pacific sardine), for the fishing year, which runs from July 1, 2021, through June 30, 2022. This final rule will prohibit most directed commercial fishing for Pacific sardine off the coasts of Washington, Oregon, and California. Pacific sardine harvest will be allowed only in the live bait fishery, minor directed fisheries, as incidental catch in other fisheries, or as authorized under exempted fishing permits. The incidental harvest of Pacific sardine will be limited to 20 percent by weight of all fish per trip when caught with other stocks managed under the Coastal Pelagic Species Fishery Management Plan, or up to 2 metric tons per trip when caught with non-Coastal Pelagic Species stocks. The annual catch limit for the 2021–2022 Pacific sardine fishing year is 3,329 metric tons. This final rule is intended to conserve and manage the Pacific sardine stock off the U.S. West Coast.

DATES: Effective July 6, 2021.

FOR FURTHER INFORMATION CONTACT: Taylor Debevec, West Coast Region, NMFS, (562) 619–2052, *Taylor.Debevec@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Pacific sardine fishery in the U.S. exclusive economic zone (EEZ) off the Pacific coast (California, Oregon, and Washington) in accordance with the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The FMP and its implementing regulations require NMFS to set annual catch levels for the Pacific sardine fishery based on the annual specification framework and control rules in the FMP. These control rules include the harvest guideline (HG) control rule, which, in conjunction with the overfishing limit (OFL) and acceptable biological catch (ABC) rules in the FMP, are used to manage harvest levels for Pacific sardine, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (MSA), 16 U.S.C. 1801 *et seq.*

This final rule implements the annual catch levels, reference points, and management measures for the 2021–2022 fishing year. The final rule adopts, without changes, the catch levels and restrictions that NMFS proposed in the rule published on May 26, 2021. The proposed rule for this action included additional background on the specifications and details of how the Pacific Fishery Management Council (Council) derived its recommended specifications for Pacific sardine. Those details are not repeated here. For additional information on this action, please refer to the proposed rule (86 FR 28325).

This rule implements an OFL of 5,525 metric tons (mt) and an ABC/annual catch limit (ACL) of 3,329 mt, based on CPS FMP control rules and a biomass estimate of Pacific sardine of 28,276 mt. This biomass estimate is from the 2020 benchmark stock assessment and was recommended for use this year by the Council's Scientific and Statistical Committee after identifying significant uncertainties in the 2021 catch-only projection. Because the estimated biomass is less than the value of the CUTOFF parameter in the CPS FMP (150,000 mt), the harvest guideline is set to 0 mt, meaning there is no primary directed fishery for Pacific sardine. This is the seventh consecutive year the primary directed fishery has been closed. Because the estimated biomass is below the minimum stock size threshold (50,000 mt) the FMP requires that incidental catch of Pacific sardine in other CPS fisheries be limited to an incidental allowance of no more than 20 percent by weight. Although these management measures, triggered by the FMP, are expected to keep catch far below the ACL as they have done in recent history, this rule also implements an annual catch target (ACT) of 3,000 mt and implements management measures to ensure harvest opportunity throughout the year.

A summary of the 2021–2022 fishing year specifications can be found in Table 1, and management measures in the list below.

TABLE 1—HARVEST SPECIFICATIONS FOR THE 2021–2022 SARDINE FISHING YEAR IN METRIC TONS

[mt]

Biomass estimate	OFL	ABC	HG	ACL	ACT
28,276	5,525	3,329	0	3,329	3,000

Measures for commercial sardine harvest during the 2021–2022 fishing year:

(1) If landings in the live bait fishery reach 1,800 mt of Pacific sardine, then a 1-mt per-trip limit of sardine would apply to the live bait fishery.

(2) An incidental per-landing limit of 20-percent (by weight) Pacific sardine applies to other CPS primary directed fisheries (*e.g.,* Pacific mackerel).

(3) If the ACT of 3,000 mt is attained, then a 1-mt per-trip limit of Pacific sardine would apply to all CPS fisheries (*i.e.,* 1) and 2) would no longer apply).

(4) An incidental per-landing allowance of 2 mt of Pacific sardine would apply to non-CPS fisheries until the ACL is reached.

All sources of catch, including any exempted fishing permit (EFP) set-asides, the live bait fishery, and other minimal sources of harvest, such as incidental catch in CPS and non-CPS fisheries and minor directed fishing, will be accounted for against the ACT and ACL. At the April 2021 Council meeting, the Council approved 830 mt of the ACL for three EFP proposals to support stock assessments for Pacific sardine. Any Pacific sardine harvested between July 1, 2021, and the effective date of the final rule will count toward the 2021–2022 ACT.

The NMFS West Coast Regional Administrator will publish a notification in the **Federal Register** to announce when catch reaches the incidental limits as well as any changes to allowable incidental catch percentages. Additionally, to ensure that the regulated community is informed of any closure, NMFS will make announcements through other means available, including emails to fishermen, processors, and state fishery management agencies.

Comments and Responses

On May 26, 2021, NMFS published a proposed rule for this action and solicited public comments through June 10, 2021 (86 FR 28325). NMFS received one public comment letter containing multiple comments from the environmental group Oceana. After considering the public comment, NMFS made no changes from the proposed rule. NMFS summarizes and responds to the comment letter from Oceana below.

Comment: Oceana states that the proposed harvest specifications are not based on the best available science, fail to prevent overfishing, and will impede rebuilding. Oceana requests that NMFS revise the proposed specifications to reduce catch limits. Specifically, Oceana suggests that NMFS use a different E_{MSY} value to calculate the OFL, ABC, and ACL, which would result in an OFL of 1,230 mt, an ABC of 741 mt, and an ACL lower than 741 mt. Oceana also suggests that NMFS reduce catch by limiting live bait harvest of sardine, denying EFP applications that propose to land or sell sardine or limiting their catch to 10 mt, and limiting incidental catch of sardine in other directed CPS fisheries to no more than 10 percent of landings.

Response: NMFS has determined this action is based on the best available science, prevents overfishing, and will not impede rebuilding. NMFS disagrees with Oceana's suggestion that setting a lower ACL, specifically an ACL lower than 741 mt, is necessary to prevent overfishing. The reference points being implemented through this action were recommended by the Council based on the control rules in the FMP and were endorsed by the Council's Scientific and Statistical Committee (SSC) as the best scientific information available for setting the 2021–2022 harvest specifications for Pacific sardine. In addition, the management measures adopted by the Council, including an ACT that was set even lower than the ACL (3,000 mt), are more than adequate to ensure catch does not exceed the ACL/ABC and OFL, and therefore add an additional measure for preventing overfishing. Furthermore, although the SSC did not endorse the 2021 catch-only projection due to uncertainty in the model (including the level of catch by Mexico), more precaution was built into the Council's ABC recommendation to account for this uncertainty and to ensure overfishing is prevented. The reference points implemented through this action should also be viewed in the context of the non-discretionary harvest restrictions already in place, pursuant to the CPS FMP, which generally restrict the fishery from catching the full ACL. These non-discretionary restrictions include the continued closure of the primary directed fishery (*i.e.,* the largest fishery that takes the majority of Pacific sardine catch) and restrictions on incidental harvest of Pacific sardine in other CPS fisheries (which are currently less than half of typical incidental limits).

NMFS also finds it unnecessary to further limit the landings of sardine by implementing any of the additional measures recommended by Oceana—*i.e.,* limiting live bait harvest, denying EFP applications or limiting their allowable catch, and reducing the percentage of landings allowed in other directed CPS fisheries. The Council considered the overfished status of Pacific sardine, as well as the uncertainty around the 2021 catch update due to the inability to collect survey data during the COVID–19 pandemic, and incorporated precautionary measures in their recommendations to NMFS to account for those factors. Those precautionary measures included: (1) Deeming the assessment Tier 3 (high uncertainty); (2) using a P* value of 0.4 (high uncertainty); (3) reducing the ACT from the ACL; (4) reducing the EFP allowance from the requested amount; (5) limiting incidental sardine landings in CPS fisheries to 20 percent; and (6) incorporating accountability measures. These accountability measures include: (1) Limiting live bait landings to 1 mt per landing once 1,800 mt of sardine is attained; (2) imposing a per-trip limit of 1 mt of sardine in all CPS fisheries once the ACT is attained; and (3) implementing an incidental per-landing allowance of 2 mt in non-CPS fisheries until the ACL is reached.

Finally, although changes to how E_{MSY} is calculated is beyond the scope of this rulemaking, NMFS would nevertheless like to respond to Oceana's suggestion in this regard. NMFS is aware of the 2019 scientific publication referenced by Oceana in their comment letter and of ongoing Council discussions related to E_{MSY}. NMFS is committed to participating in discussions about new science and whether that science justifies a change to how E_{MSY} is calculated for management purposes. Regarding the 2019 paper mentioned by Oceana that was authored by researchers at the SWFSC, NMFS notes that research related to the appropriate temperature

index to inform E_{MSY} is ongoing. NMFS has not yet determined whether, based on that paper, a change in how E_{MSY} is calculated is necessary for management purposes. NMFS will continue to examine whether this new publication warrants a change in management; however, at this time NMFS has determined that the reference points set through this action are based on the best scientific information available. Regarding recent Council discussions related to E_{MSY}, NMFS notes that the Council's SSC—the scientific advisory body that is responsible for recommending changes to E_{MSY}—has the ability to recommend changes to E_{MSY} at any time, and it has not determined that a change is necessary at this time. The Council's SSC previously made such a recommendation in 2014 when it recommended that NMFS switch from using the 3-year average of Scripps Institution of Oceanography (SIO) sea surface temperature measurements to using the 3-year average of CalCOFI sea surface temperature measurements to inform E_{MSY}. In 2014 the SSC also recommended an interim measure of a static E_{MSY} of 18 percent until that change, from SIO to CalCOFI, could be adopted after being properly analyzed.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this final rule is consistent with the CPS FMP, other provisions of the MSA, and other applicable law.

The need to implement these measures in a timely manner to ensure they are in place as soon as possible after the start of the fishing season, July 1, 2021, constitutes good cause under authority contained in 5 U.S.C. 553(d)(3), to establish an effective date less than 30 days after date of publication. In accordance with the FMP, this rule was recommended by the Council at its meeting in April 2021, the contents of which were based on the best available new information on the population status of Pacific sardine that became available at that time. Making these final specifications effective as soon as possible after July 1, the first day of the fishing year, is necessary for the conservation and management of the Pacific sardine resource because last year's restrictions on harvest are not effective after June 30. The FMP requires a prohibition on primary directed fishing for Pacific sardine for the 2021–2022 fishing year because the sardine biomass has dropped below the CUTOFF. The purpose of the CUTOFF in the FMP, and for prohibiting a primary directed fishery when the biomass drops below this level, is to protect the stock when biomass is low and provide a buffer of spawning stock that is protected from fishing and can contribute to rebuilding the stock. A delay of a full 30 days in the date of effectiveness for this rule would result in the re-opening of the primary directed commercial fishery on July 1.

Delaying the effective date of this rule much beyond July 1 would be contrary to the public interest because it would jeopardize the sustainability of the Pacific sardine stock. Furthermore, most affected fishermen are aware that the Council recommended that primary directed commercial fishing be prohibited for the 2021–2022 fishing year, and are fully prepared to comply with the prohibition.

This final rule is exempt from review under 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 action would not have a significant economic impact on a substantial number of small entities for the purposes of the Regulatory Flexibility Act. The factual basis for the certification was published in the proposed rule and is not repeated here. As a result, a regulatory flexibility analysis was not required, and none was prepared.

Pursuant to Executive Order 13175, this rule was developed after meaningful consultation and collaboration with the Council's tribal representative, who has agreed with the provisions that apply to tribal vessels.

This action does not contain a collection-of-information requirement for purposes of the Paper Reduction Act. There are no relevant Federal rules that may duplicate, overlap, or conflict with the action.

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

Dated: July 6, 2021.

Samuel D. Rauch, III,

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

[FR Doc. 2021–14643 Filed 7–6–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 210701–0142]

RIN 0648–BK28

Pacific Island Fisheries; Exemption for Large U.S. Longline Vessels To Fish in Portions of the American Samoa Large Vessel Prohibited Area; Court Order

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

ACTION: Final rule.

SUMMARY: NMFS implements a regulatory exemption that allows certain U.S. longline vessels 50 ft (15.2 m) and larger (''large longline vessels'') to fish in portions of the American Samoa Large Vessel Prohibited Area (LVPA). The intent is to comply with a U.S. Ninth Circuit Court of Appeals decision and Order that reversed a district court ruling that had vacated and set aside the exemption.

DATES: Effective July 6, 2021.

FOR FURTHER INFORMATION CONTACT: Bob Harman, NMFS PIRO Sustainable Fisheries, 808–725–5170.

SUPPLEMENTARY INFORMATION: NMFS and the Western Pacific Fishery Management Council (Council) manage pelagic fisheries in the U.S. Pacific Islands under the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific Region. In 2016, NMFS published a final rule (81 FR 5619, February 3, 2016) that allowed U.S. longline vessels greater than 50 feet that hold a Federal American Samoa longline limited entry permit to fish within the LVPA to within about 12–17 nm (22–31 km) from shore around Swains Island, Tutuila, and the Manua Islands. Large longline vessels continued to be restricted from fishing within the remaining portions of the LVPA. The intent of the rule was to improve the viability of the American Samoa longline fishery and achieve optimum yield, while preventing overfishing in accordance with National Standard 1 of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Additional information about the LVPA exemptions is available in the proposed rule (80 FR 51527, August 25, 2015) and final rule.

In July 2016, the Territory of American Samoa sued NMFS in the U.S. District Court for the District of Hawaii (*Territory of American Samoa* v. *NMFS,*

et al. (D. HI) Civil 16–00095), seeking to set aside the 2016 final rule. The Territory claimed that NMFS did not consider, as other applicable law, the 1900 and 1904 Cessions with respect to the protection of cultural fishing rights of the people of American Samoa. On March 20, 2017, the U.S. District Court for the District of Hawaii held that the 2016 final rule was arbitrary and capricious because NMFS did not consider whether the rule and its impacts on cultural fishing were consistent with the Cessions. On August 10, 2017, the U.S. District Court denied Defendants' Motion for Reconsideration of this decision. Accordingly, NMFS published a final rule (82 FR 43908, September 20, 2017) that removed the regulatory exemption that allowed large vessels to fish within certain areas of the LVPA.

NMFS appealed the district court decision to the U.S. Court of Appeals for the Ninth Circuit (*Territory of American Samoa* v. *NMFS et al.,* No. 17–17081 (9th Cir.)). On September 25, 2020, a 9th Circuit Court panel unanimously held that NMFS had properly considered the impact of the 2016 LVPA rule on cultural fishing and fishing communities, regardless of whether it specifically considered the Cessions. American Samoa subsequently filed a petition for a writ of certiorari, which on June 21, 2021, the Supreme Court denied. Pursuant to the 9th Circuit Court mandate on November 17, 2020, this final rule reinstates the LVPA exemptions established in the 2016 final rule (81 FR 5619, and codified at 50 CFR 665.818(b)). This rule allows U.S. large longline vessels that hold a Federal American Samoa longline limited entry permit to fish within the LVPA to approximately 12–17 nm from the shoreline around Swains Island, Tutuila, and the Manua Islands. All other provisions applicable to the fishery remain unchanged.

Classification

NMFS is issuing this rule pursuant to 305(d) of the Magnuson-Stevens Act because this action is necessary to carry out the Ninth Circuit Order. The Assistant Administrator for Fisheries has determined that this final rule is consistent with the Ninth Circuit Order, the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific, and other applicable law.

The Assistant Administrator for Fisheries finds good cause to waive notice and public comment on this action because it would be unnecessary and contrary to the public interest, as provided by 5 U.S.C. 553(b)(B). This action reinstates an exemption that was implemented by prior rulemaking, including the opportunity for notice and comment, and that was set aside by a district court. That district court decision has been reversed by the Ninth Circuit Court of Appeals. NMFS does not have discretion to take other action, as there is no alternative to complying with the requirements of the Ninth Circuit Order.

Furthermore, the Assistant Administrator for Fisheries finds good cause to waive the 30-day delayed effectiveness period, as provided by 5 U.S.C. 553(d)(3), finding that such delay would be contrary to the public interest because the measures contained in this rule are necessary to ensure that the fishery is conducted in compliance with the Ninth Circuit Order.

Because this rulemaking is required by a Ninth Circuit Order, and prior notice and opportunity for public comment are not required under 5 U.S.C. 553, or any other law, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 603–605, do not apply to this rule. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

In addition, because the changes required by the Ninth Circuit Order identified in this rule are non-discretionary, the National Environmental Policy Act does not apply to this rule.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

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

List of Subjects in 50 CFR Part 665

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: July 6, 2021.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 665 as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 1. The authority citation for 50 CFR part 665 continues to read as follows:

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

■ 2. In § 665.818, add paragraph (b) to read as follows:

§ 665.818 Exemptions for American Samoa large vessel prohibited areas.

* * * * *

(b) *Exemption for vessel size.* Except as otherwise prohibited in subpart I of this part, a vessel of any size that is registered for use with a valid American Samoa longline limited access permit is authorized to fish for western Pacific pelagic MUS within the American Samoa large vessel prohibited areas as defined in § 665.806(b), except that no large vessel as defined in § 665.12 may be used to fish for western Pacific pelagic MUS in the portions of the American Samoa large vessel prohibited areas, as follows:

(1) EEZ waters around Tutuila Island enclosed by straight lines connecting the following coordinates (the datum for these coordinates is World Geodetic System 1984 (WGS84)):

Point	S. lat.	W. long.
TU–1	14°01′42″	171°02′36″
TU–2	14°01′42″	170°20′22″
TU–3	14°34′31″	170°20′22″
TU–4	14°34′31″	171°03′10″
TU–5	14°02′47″	171°03′10″
TU–1	14°01′42″	171°02′36″

(2) EEZ waters around the Manua Islands enclosed by straight lines connecting the following coordinates (WGS84):

Point	S. lat.	W. long.
MA–1	13°57′16″	169°53′37″
MA–2	13°57′16″	169°12′45″
MA–3	14°28′28″	169°12′45″
MA–4	14°28′28″	169°53′37″
MA–1	13°57′16″	169°53′37″

(3) EEZ waters around Swains Island enclosed by straight lines connecting the following coordinates (WGS84):

Point	S. lat.	W. long.
SW–1	10°50′42″	171°17′42″
SW–2	10°50′42″	170°51′39″
SW–3	11°16′08″	170°51′39″
SW–4	11°16′08″	171°17′42″
SW–1	10°50′42″	171°17′42″

[FR Doc. 2021–14623 Filed 7–6–21; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 129
Friday, July 9, 2021

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0498; Project Identifier 2019–SW–072–AD]

RIN 2120–AA64

Airworthiness Directives; Hélicoptères Guimbal Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Hélicoptères Guimbal Model Cabri G2 helicopters with any metal bushing installed on the main rotor (M/R) swashplate guide bellcrank. This proposed AD was prompted by a report of cracks discovered on the M/R scissor link during scheduled maintenance on several helicopters. This proposed AD would require removing all metal bushings from service, visually inspecting the lug bore area and depending on the inspection results, removing certain parts from service and installing certain part-numbered plastic bushings. This proposed AD would also prohibit installing any metal bushing on any helicopter. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 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 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Hélicoptères Guimbal, Basile Ginel, 1070, rue du Lieutenant Parayre, Aérodrome d'Aix-en-Provence, 13290 Les Milles, France; telephone 33–04–42–39–10–88; email *basile.ginel@guimbal.com;* web *https://www.guimbal.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0498; 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 European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Mail Stop: Room 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0498; Project Identifier 2019–SW–072–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 this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0185, dated July 30, 2019 (EASA AD 2019–0185), to correct an unsafe condition for Hélicoptères Guimbal Model Cabri G2 helicopters. EASA advises that during scheduled maintenance on several helicopters, cracks were found on the M/R scissor link due to corrosion. EASA states this corrosion was caused by stress induced by the mounting of the metal bushing inside the lug hole. EASA further states metal bushings are also installed on the M/R swashplate guide bellcrank, where similar cracking may occur. This condition, if not addressed,

could result in failure of the M/R swashplate guide bellcrank and reduced control of the helicopter. Accordingly, EASA AD 2019–0185 requires replacing any part-numbered metal bushing with plastic bushing part number (P/N) HG22–1001. EASA AD 2019–0185 also prohibits installing any part-numbered metal bushing on the M/R swashplate guide bellcrank other than P/N HG22–1001 on any helicopter.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type designs.

Related Service Information

The FAA reviewed Guimbal Service Bulletin SB 17–003, Revision D, dated August 27, 2019 (SB 17–003 Rev D). This service information specifies disconnecting the bellcrank installed on the swashplate guide by removing the bolts that connect the bellcrank to the swashplate guide, removing any existing bushings, and visually inspecting the lug bore area for corrosion or cracks. This service information also specifies if there is any corrosion or cracks, reporting the information to HG support, installing the new plastic bushings, reinstalling the bellcrank, applying a specified torque, and installing cotter pins.

Other Related Service Information

The FAA also reviewed Guimbal Service Bulletin SB 17–003, Revision C, dated July 12, 2019 (SB 17–003 Rev C). SB 17–003 Rev C specifies the same procedures as SB 17–003 Rev D, except SB 17–003 Rev D updates the reference to EASA AD 2019–0185.

Proposed AD Requirements in This NPRM

This proposed AD would require, within 50 hours time-in-service or 2 months, whichever occurs first after the effective date of this AD, disconnecting the bellcrank from the swashplate guide, removing each bolt and using a certain tool, removing certain parts from service. This proposed AD would also require visually inspecting the lug bore area for corrosion and cracks and depending on the inspection results, removing certain parts from service, or repairing the area using an FAA-approved method, installing certain part-numbered plastic bushings, coating the area with a compound, reinstalling certain parts, applying a specified torque, and installing cotter pins.

Differences Between This Proposed AD and the EASA AD

EASA AD 2019–0185 applies to all Model Cabri G2 helicopters, whereas this proposed AD would only apply to Model Cabri G2 helicopters with any metal bushings installed and without HG modification 16–009. The service information required by the EASA AD requires contacting Hélicoptères Guimbal for corrective actions when corrosion or cracks are found in the lug bore area whereas this AD requires removing the swashplate guide from service or repairing it using an FAA-approved method.

Costs of Compliance

The FAA estimates that this proposed AD would affect 32 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this proposed AD. Labor costs are estimated at $85 per work-hour.

Disconnecting the bellcrank, removing each metal bushing and visually inspecting for corrosion and cracks would take about 0.5 work-hours for an estimated cost of $43 per inspection cycle.

Installing each plastic bushing, coating with compound, re-installing the bellcrank, and applying torque would take about 0.5 work-hours and parts would cost about $10 for an estimated cost of $53 per helicopter.

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, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Hélicoptères Guimbal: Docket No. FAA–2021–0498; Project Identifier 2019–SW–072–AD.

(a) Comments Due Date

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

(b) Affected ADs

None.

(c) Applicability

This AD applies to Hélicoptères Guimbal (HG) Model Cabri G2 helicopters, certificated in any category, with any metal bushings installed on the main rotor (M/R) swashplate guide bellcrank and without plastic bushing part number HG22–1001 or HG modification 16–009.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft Flight Control.

(e) Unsafe Condition

This AD was prompted by a report of cracks on the M/R scissor link. The FAA is issuing this AD to replace the metal bushings installed on the M/R swashplate guide bellcrank with plastic bushings. The unsafe condition, if not addressed, could result in failure of the M/R swashplate guide bellcrank and reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 50 hours time-in-service (TIS) or 2 months, whichever occurs first after the effective date of this AD:

(i) Disconnect the bellcrank from the swashplate guide by removing each bolt and, ensuring that the bellcrank remains attached to the flight control rod, remove each metal bushing from service using a bushing disassembly tool.

(ii) Visually inspect the lug bore area for any corrosion and any cracks. If there is any corrosion or any cracks, before further flight, remove the swashplate guide from service or repair it using an FAA-approved method. If there is no corrosion and no cracks, install plastic bushing part number HG22–1001, coat plastic bushing with isolation compound, re-install the bellcrank, torque each bolt to 7.5 Nm–9 Nm (5.5 ft-lbs–6.6 ft-lbs), and install cotter pins.

(2) As of the effective date of this AD, do not install any metal bushing on any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (i)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-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.

(i) Related Information

(1) For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

(2) Guimbal Service Bulletin SB 17–003, Revision C, dated July 12, 2019, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Hélicoptères Guimbal, Basile Ginel, 1070, rue du Lieutenant Parayre, Aérodrome d'Aix-en-Provence, 13290 Les Milles, France; telephone 33–04–42–39–10–88; email *basile.ginel@guimbal.com;* web *https://www.guimbal.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2019–0185, dated July 30, 2019. You may view the EASA AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2021–0498.

Issued on June 10, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–14495 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0560; Project Identifier MCAI–2021–00192–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by reports that the sliding bushings in the forward engine mount system were missing. This proposed AD would require an inspection (gap check) of the front and aft engine mounts to verify the proper installation of the sliding bushings, and repair if necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 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 Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* internet *https://www.bombardier.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.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0560; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0560; Project Identifier MCAI–2021–00192–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email *9-avs-nyaco-cos@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

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2021–04, dated February 15, 2021 (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0560.

This proposed AD was prompted by reports that the sliding bushings in the forward engine mount system were missing. The FAA is proposing this AD to address redistribution of load/stress on the mount components, which may decrease the component fatigue life; failure of the mount structural components could result in the loss of the engine attachment to the airframe. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc., has issued the following service information.

- Bombardier Service Bulletin 700–1A11–71–005, dated December 14, 2020.
- Bombardier Service Bulletin 700–71–005, dated December 14, 2020.
- Bombardier Service Bulletin 700–71–5005, dated December 14, 2020.
- Bombardier Service Bulletin 700–71–5501, dated December 14, 2020.
- Bombardier Service Bulletin 700–71–6005, December 14, 2020.
- Bombardier Service Bulletin 700–71–6501, December 14, 2020.

This service information describes procedures for verifying the proper installation of the sliding bushings by doing an inspection (gap check), including a gap outside acceptable limits, a missing or damaged nut or bolt at the upper side of front mount beam, and a bolt that turns freely with finger pressure. These documents are distinct since they apply to different airplane serial numbers. 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 the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 376 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
11 work-hours × $85 per hour = $935	$0	$935	$351,560

The FAA has received no definitive data on which to base the cost estimates for the repairs specified in this proposed AD.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2021–0560; Project Identifier MCAI–2021–00192–T.

(a) Comments Due Date

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

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9002 through 9879 inclusive, 9998, 60001 through 60005 inclusive, 60007, 60009, 60015, 60016, and 60024.

(d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

(e) Unsafe Condition

This AD was prompted by reports that the sliding bushings in the forward engine mount system were missing. The FAA is issuing this AD to address redistribution of load/stress on the mount components, which may decrease the component fatigue life; failure of the mount structural components could result in the loss of the engine attachment to the airframe.

(f) Compliance

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

(g) Inspection and Corrective Action

Within 15 months or 750 flight hours, whichever occurs first, after the effective date of this AD: Verify the proper installation of the sliding bushings by doing an inspection (gap check) for discrepancies of the front and aft engine mounts, in accordance with paragraphs 2.B. through 2.F. of the Accomplishment Instructions of the applicable service information specified in figure 1 to paragraph (g) of this AD. If any discrepancy is found: Before further flight, repair using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature. Where a serial number is identified in more than one row in figure 1 to paragraph (g) of this AD, the applicable service information is identified based on the marketing designations in paragraph 1.M., ''Equivalent Service Bulletins,'' of each service information.

BILLING CODE 4910–13–P

Figure 1 to paragraph (g) – *Service Information*

Serial Number–	Model–	Bombardier Service Bulletin–
9002 to 9312 inclusive, 9314 to 9380 inclusive, and 9384 to 9429 inclusive	BD-700-1A10 airplanes	700-71-005, dated December 14, 2020
9313, 9381, 9432 to 9860 inclusive, 9863 to 9871 inclusive, 9873 to 9879 inclusive, 60005 and 60024	BD-700-1A10 airplanes	700-71-6005, December 14, 2020
9861, 9872, 60001 to 60004 inclusive, 60009, and 60016	BD-700-1A10 airplanes	700-71-6501, December 14, 2020
9127 to 9383 inclusive, 9389 to 9400 inclusive, 9404 to 9431inclusive, and 9998	BD-700-1A11 airplanes	700-1A11-71-005, dated December 14, 2020
9386, 9401, 9445 to 9862 inclusive, and 9868 to 9879 inclusive	BD-700-1A11 airplanes	700-71-5005, dated December 14, 2020
60007 and 60015	BD-700-1A11 airplanes	700-71-5501, dated December 14, 2020

BILLING CODE 4910–13–C

(h) No Reporting Requirement

Although the service information identified in table 1 to paragraph (g) of this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* 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 responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. 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, New York ACO Branch, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2021–04, dated February 15, 2021; for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0560.

(2) For more information about this AD, contact Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* internet *https://www.bombardier.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.

Issued on July 2, 2021.

Gaetano A. Sciortino,

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

[FR Doc. 2021–14611 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

POSTAL REGULATORY COMMISSION

39 CFR Chapter III

[Docket No. PI2021–2; Order No. 5930]

Public Inquiry

AGENCY: Postal Regulatory Commission.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Commission seeks further input from the public about what regulations promulgated by the Commission may be necessary to carry out the requirements of agency law. This document informs the public of this proceeding, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 26, 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. Background
III. Discussion
IV. Comments
V. Ordering Paragraphs

I. Introduction

In this docket, the Commission seeks further input from the public about what regulations promulgated by the Commission may be necessary to carry out the requirements of 39 U.S.C. 601. Section 601 describes instances when letters may be carried out of the mail, or when the letter monopoly does not apply to a mailpiece. In particular, the Commission seeks to determine whether regulations promulgated by the Commission are needed to carry out those statutory exemptions.

II. Background

The Postal Service has exclusive rights in the carriage and delivery of letters under certain circumstances. This letter monopoly is codified in the Private Express Statutes (PES), which are a group of civil and criminal statutes that make it unlawful for any entity other than the Postal Service to send or carry letters. *See* 18 U.S.C. 1693–1699; 39 U.S.C. 601–606.[1]

Section 601 provides specific instances (exceptions) where letters may be carried out of the mail (*i.e.,* not subject to the letter monopoly). Section 601(a) sets forth the conditions under which a letter may be carried out of the mail, which include requiring that the letter be enclosed in an envelope, that the proper amount of postage is affixed to the envelope, and that the postage is canceled. 39 U.S.C. 601(a).

Section 601(b) provides additional exceptions such that the letter monopoly does not apply to letters charged more than six times the current rate for the first ounce of a Single-Piece First Class Letter or to letters weighing more than 12.5 ounces. *See* 39 U.S.C. 601(b)(1), (b)(2). The ''grandfather clause'' in Section 601(b)(3) references exceptions from prior Postal Service regulations that permitted private carriage as in effect on July 1, 2005. 39 U.S.C. 601(b)(3); *see also* 39 CFR 310.1 and 39 CFR 320.2–320.8 (2005).

Section 601(c), which is the subject of this proceeding, directs the Commission (rather than the Postal Service) to promulgate any regulations necessary to carry out this section. 39 U.S.C. 601(c). This Public Inquiry seeks to answer how the Commission shall meet this statutory requirement.

Prior to the Postal Accountability and Enhancement Act (PAEA) of 2006, the Postal Service issued regulations that purported to suspend the PES.[2] The PAEA included the term ''purport'' to describe the Postal Service's efforts to suspend the PES, reflecting some disagreement between the Postal Service and policymakers about the Postal Service's authority to promulgate such regulations prior to the PAEA.[3] Post-PAEA, the law clearly cedes such authority to the Commission. These regulations defined the term ''letter'' as ''a message directed to a specific person or address and recorded in or on a tangible object,'' subject to several provisions. 39 CFR 310.1(a) (2005). The regulations also described several statutory exceptions to the letter monopoly, such as when the letter accompanies and relates to cargo or when a special messenger is used. *See* 39 CFR 310.3 (2005). In addition, the

[1] Although these provisions of the U.S. Code are customarily referred to collectively as the ''Private Express Statutes,'' they do not all relate to private expresses or prohibit carriage of letters out of the mails.

[2] *See* Postal Accountability and Enhancement Act, Public Law 109–435, 120 Stat. 3198 (2006); *see also* 39 CFR 310, 320 (2005).

[3] *See* H.R. Rep. No. 109–66, 109th Cong., 1st Sess., pt. 1, at 58 (2005) (H.R. Rep. No. 109–66).

regulations purported to establish administrative suspensions of the PES (39 CFR 310.1(a)(7) n.1, 320 (2005)), including suspensions for certain data processing materials or for extremely urgent letters. *See* 39 CFR 320.2, 320.6 (2005).

These regulations were originally promulgated by the Postal Service in 1974 and were amended several times prior to enactment of the PAEA.[4] In 2003, the President's Commission on the United States Postal Service recommended that the scope of the letter monopoly should be clarified and periodically reviewed by a Postal Regulatory Board.[5] In 2006, Congress passed the PAEA, which, inter alia, added new price and weight limits to the postal monopoly, repealed the Postal Service's purported authority to adopt administrative suspension of the monopoly, and repealed the Postal Service's authority to implement provisions of the criminal code defining the scope of the monopoly.[6]

In addition to adding price and weight limits as exceptions (Sections 601(b)(1), (b)(2)), Congress also added a ''grandfather clause'' in Section 601(b)(3) to authorize the continuation of private activities that the Postal Service had purportedly permitted by regulations to be carried out of the mail. The House Report on the PAEA explains that this paragraph protects mailers and private carriers who had relied upon the regulations adopted as of the date of the bill. *See* H.R. Rep. No. 109–66 at 58. Congress also eliminated the Postal Service's authority to adopt any regulations creating exceptions or defining the scope of the postal monopoly. *See* 39 U.S.C. 401(2), 404(a)(1), 601. Congress instead gave the Commission the authority to promulgate ''[a]ny regulations necessary to carry out this section [601].''[7] To date, the Commission has not promulgated any regulations pursuant to Section 601(c).

In Docket No. RM2020–4, the Commission issued an advance notice of proposed rulemaking to seek input from the public about what regulations promulgated by the Commission may be necessary to carry out the requirements of 39 U.S.C. 601.[8] In particular, the Commission sought comments on fourteen issues, such as whether the statutory requirements of Section 601 are clear and concise, whether any terms in the statute required further definition, and whether consumers and competitors can easily determine when a mailpiece is subject to monopoly protections. Order No. 5422 at 7–8.

Prior to the comment deadline, the Commission issued two Chairman's Information Requests, regarding certain Postal Service regulations.[9] In its response, the Postal Service explained that it had not issued regulations or other administrative directives in connection with Sections 601(b)(1) and (2) since the effective date of amended Section 601(b).[10] The Postal Service also provided information regarding alternative payment agreements pursuant to 39 CFR 310.2(b).[11] In addition, the Postal Service provided information regarding advisory opinions pursuant to 39 CFR 310.6. Docket No. RM2020–4, Response to CHIR No. 1, question 2.

Comments were received from The Berkshire Company; Taxpayers Protection Alliance; American Consumer Institute Center for Citizen Research; United Parcel Service, Inc.; FedEx Corporation; Netflix, Inc.; Small Business & Entrepreneurship Council; the National Postal Policy Council and the National Association of Presort Mailers; the Association for Postal Commerce; the Postal Service; and the Public Representative.[12] Based on the comments received, the Commission found it necessary to gather more information from the public before promulgating regulations under Section 601 and therefore, that proceeding is held in abeyance until the conclusion of this inquiry.[13]

III. Discussion

In this proceeding, the Commission seeks to focus its inquiry on the statutory exemptions in Sections 601(a) and (b), and what regulations under Section 601(c), if any, are needed to carry out those exemptions. In particular, the Commission limits this inquiry to two issues: (1) Whether Postal Service regulations administering current Sections 601(a), 601(b)(1), and 601(b)(2) should be adopted by the Commission; and (2) what private carrier services are within the scope of Section 601(b)(3).

First, the Commission is interested in identifying Postal Service regulations that administer Sections 601(a), 601(b)(1), and 601(b)(2) and if the Commission should adopt them. Section 601(a) provides for the private carriage of letters when, among other things, the letter is in an envelope that is properly addressed, the proper amount of postage is affixed to the envelope, and the postage is canceled in ink by the sender. 39 U.S.C. 601(a). Sections 601(b)(1) and (b)(2) further provide that a letter must meet price and weight requirements in order to be carried out of the mail. 39 U.S.C. 601(b)(1), 601(b)(2).

Prior to the PAEA, the Postal Service issued regulations concerning the restrictions on the private carriage of

[4] *See* Comprehensive Standards for Permissible Private Carriage, 39 FR 33211 (Sept. 16, 1974).

[5] Report of the President's Commission on the United States Postal Service, *Embracing the Future: Making the Tough Choices to Preserve Universal Mail Service,* July 31, 2003, at 71 (President's Commission). The President's Commission recommended ''transforming the narrowly focused Postal Rate Commission [ ] into an independent Postal Regulatory Board.'' *Id.* at XIII.

[6] *See* H.R. Rep. No. 109–66 at 57. Congress stated that ''the bill clarifies the scope of the statutory monopoly that historically has been defined solely by the [Postal Service].'' *Id.* at 58.

[7] 39 U.S.C. 601(c). *See* Docket Nos. MC2012–14 and R2012–8, Order Approving Addition of Valassis Direct Mail, Inc. Negotiated Service Agreement to the Market Dominant Product List, August 23, 2012, at 6–7 (Order No. 1448) (citing Section 601(c) and stating that the Postal Service no longer has authority to issue regulations interpreting or defining the postal monopoly); *see also* Docket No. MC2012–13, Order Conditionally Granting Request to Transfer Parcel Post to the Competitive Product List, July 20, 2012, at 6–7 (Order No. 1411) (''As a result of the PAEA, the Postal Service no longer has authority to issue regulations interpreting or defining the postal monopoly. The Commission now has the authority to promulgate such regulations.''). Order No. 1411 at 7 n.13.

[8] *See* Docket No. RM2020–4, Advance Notice of Proposed Rulemaking to Consider Regulations to Carry Out the Statutory Requirements of 39 U.S.C. 601, February 7, 2020 (Order No. 5422).

[9] Docket No. RM2020–4, Chairman's Information Request No. 1, March 4, 2020 (Docket No. RM2020–4, CHIR No. 1); Docket No. RM2020–4, Chairman's Information Request No. 2, April 1, 2020 (Docket No. RM2020–4, CHIR No. 2).

[10] Docket No. RM2020–4, Responses of the United States Postal Service to Questions 1–3 of Chairman's Information Request No. 1, March 11, 2020, question 1 (Docket No. RM2020–4, Response to CHIR No. 1).

[11] Docket No. RM2020–4, Response to CHIR No. 1, question 3; *see also* Response of the United States Postal Service to Chairman's Information Request No. 2, April 3, 2020, question 1 (Docket No. RM2020–4, Response to CHIR No. 2).

[12] Docket No. RM2020–4, Comments of The Berkshire Company in Response to Order No. 5442, April 6, 2020; Docket No. RM2020–4, Comments of Taxpayers Protection Alliance, April 6, 2020; Docket No. RM2020–4, Comments of American Consumer Institute Center for Citizen Research Regarding Docket No. RM2020–4 Submitted to the United States Postal Regulatory Commission, April 6, 2020; Docket No. RM2020–4, Comments of United Parcel Service, Inc. on Advance Notice of Proposed Rulemaking to Consider Regulations to Carry Out the Statutory Requirements of 39 U.S.C. 601, April 7, 2020; Docket No. RM2020–4, Comments of FedEx Corporation, April 7, 2020; Docket No. RM2020–4, Comments of Netflix, Inc., April 7, 2020; Docket No. RM2020–4, Comments of Small Business & Entrepreneurship Council, April 7, 2020; Docket No. RM2020–4, Comments of the National Postal Policy Council and the National Association of Presort Mailers, April 7, 2020; Docket No. RM2020–4, Comments of the Association for Postal Commerce, April 7, 2020; Docket No. RM2020–4, Comments of the United States Postal Service in Response to Order No. 5422, April 7, 2020; Docket No. RM2020–4, Public Representative Comments, April 7, 2020.

[13] Docket No. RM2020–4, Order Holding Rulemaking in Abeyance, July 2, 2021 (Order No. 5929).

letters. Several of these regulations were modified and superseded by the adoption of the PAEA. For example, the PAEA supersedes a Postal Service regulation that allows private carriage if the amount paid is ''at least three dollars or twice the applicable U.S. postage for First-Class Mail (including priority mail) whichever is greater.'' 39 CFR 320.6(c). In addition, a Postal Service regulation closely tracks the language in Section 601(a) but also allows for alternative payment agreements in written agreements between customers and the Postal Service. 39 CFR 310.2(b). The Commission is specifically interested in whether certain Postal Service regulations implement the current statutory exemptions found in Sections 601(a), 601(b)(1), and 601(b)(2), and whether the Commission should adopt or revise these and other regulations to clarify the statutory exemptions.

Second, the Commission is interested in identifying what private carrier services are within the scope of Section 601(b)(3). *See* 39 U.S.C. 601(b)(3). The ''grandfather clause'' in Section 601(b)(3) authorized the continuation of private activities that the Postal Service had purportedly permitted by regulations to be carried out of the mail. Specifically, it allows private carriage that is within the scope of specific purported suspensions to the letter monopoly. 39 CFR 310.1 (2005) included twelve putative exceptions to the definition of ''letter'' and/or purported suspensions of the letter monopoly. 39 CFR 320.2–8 (2005) provided seven additional purported suspensions of the PES, including for certain data processing materials, for certain letters of college and university organizations, and for certain international-ocean carrier-related documents. The Commission seeks comments on what services were ''described by regulations of the United States Postal Service . . . that purport to permit private carriage by suspension of the operation of this section'' as of July 1, 2005. *See* 39 U.S.C. 601(b)(3). Additionally, the Commission seeks suggestions regarding what regulations may be needed to enumerate in clear terms all instances where private carrier services are within the scope of Section 601(b)(3).

For both issues, the goal of the Commission is to determine whether it is necessary to clarify the statutory exemptions regarding the letter monopoly. The Commission seeks information as to how best to resolve any ambiguities in the application of the exceptions. The Commission also inquires whether consolidating regulations and definitions under one section, rescinding redundant and/or conflicting sections, or standardizing the terminology used in the regulations would be helpful.

IV. Comments

The Commission invites interested persons to identify whether there are any Postal Service regulations that the Commission should adopt to carry out the requirements of Section 601 and if so, whether the Commission should revise those regulations. In addition, the Commission seeks comments that identify what private carrier services are within the scope of Section 601(b)(3) and whether regulations are needed to clearly enumerate those services. Commenters are encouraged to provide specific suggestions on revisions or recommend new regulations.

The Commission recognizes that comments on these issues have been provided in Docket No. RM2020–4. However, given the length of time since those comments were received and the breadth of different topics covered by the previous advance notice of proposed rulemaking, the Commission finds it prudent to solicit updated comments to assist in focusing this proceeding on a few particular issues. Commenters who previously submitted comments in Docket No. RM2020–4 may provide updated comments in this proceeding. The Commission envisions that the comments provided in this proceeding will help inform any proposed rules that may be issued in Docket No. RM2020–4.

Comments are due August 26, 2021. Material filed in this docket will be available for review on the Commission's website, *http://www.prc.gov.*

Pursuant to 39 U.S.C. 505, Kenneth E. Richardson will serve as the officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

V. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. PI2021–2 for the purpose of considering potential regulations under 39 U.S.C. 601.

2. Interested persons may submit written comments on potential regulations no later than August 26, 2021.

3. Pursuant to 39 U.S.C. 505, Kenneth E. Richardson will serve as the officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Secretary shall arrange for publication of this Notice in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2021–14636 Filed 7–8–21; 8:45 am]

BILLING CODE 7710–FW–P

Notices

Federal Register
Vol. 86, No. 129
Friday, July 9, 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

Office of the Secretary

Increase in Fiscal Year 2021 Specialty Sugar Tariff-Rate Quota

AGENCY: Office of the Secretary, U.S. Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: The Office of the Secretary of the Department of Agriculture (the Secretary) is providing notice of an increase in the fiscal year (FY) 2021 specialty sugar tariff-rate quota (TRQ) of 40,000 metric tons raw value (MTRV).

DATES: This notice is applicable on July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Souleymane Diaby, Multilateral Affairs Division, Trade Policy and Geographic Affairs, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1070, 1400 Independence Avenue SW, Washington, DC 20250–1070; by telephone (202) 720–2916; or by email *Souleymane.Diaby@usda.gov*.

SUPPLEMENTARY INFORMATION: On July 9, 2020, USDA announced the establishment of the in-quota quantity of the FY 2021 refined sugar TRQ at 162,000 MTRV for which the sucrose content, by weight in the dry state, must have a polarimeter reading of 99.5 degrees or more (85 FR 41226, July 9, 2020). This amount included the minimum level to which the United States is committed under the WTO Uruguay Round Agreements (22,000 MTRV of which 1,656 MTRV is reserved for specialty sugar) and an additional 140,000 MTRV reserved for specialty sugars. Pursuant to Additional U.S. Note 5 to Chapter 17 of the U.S. Harmonized Tariff Schedule (HTS) and Section 359k of the Agricultural Adjustment Act of 1938, as amended, the Secretary today increased the overall FY 2021 refined sugar TRQ by 40,000 MTRV to 202,000 MTRV. The increased amount is reserved for specialty sugar. Entry of this sugar will be permitted beginning July 21, 2021. The sugar entered under this tariff-rate quota is reserved for organic sugar and other specialty sugars not currently produced commercially in the United States or reasonably available from domestic sources.

Jason Hafemeister,

Acting Deputy Under Secretary, Trade and Foreign Agricultural Affairs.

[FR Doc. 2021–14726 Filed 7–7–21; 4:15 pm]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 6, 2021.

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 August 9, 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.

Animal and Plant Health Inspection Service

Title: APHIS Student Outreach Program.

OMB Control Number: 0579–0362.

Summary of Collection: Title VI of the Civil Rights Act of 1964—Nondiscrimination in Federally Assisted programs, established Special emphasis Programs throughout the Federal Government. The Animal and Plant Health Inspection Service's (APHIS') Student Outreach Program is designed to help students learn about careers in animal science, veterinary medicine, plant pathology, and agribusiness. The program allows participants to live on college campuses and learn about agricultural science and agribusiness from university professors, practicing veterinarians, and professionals working for the U.S. Government.

The Student Outreach Program is designed to enrich students' lives while they are still in their formative years. APHIS' investment in the Student Outreach Program not only exposes students to careers in APHIS, it also gives APHIS' employees the opportunity to meet and invest in APHIS' future workforce. Students chosen to participate in the Student Outreach Program will gain experience through hands-on labs, workshops, and field trips. Students will also participate in character and teambuilding activities and diversity workshops. Two programs currently in the Student Outreach Program are AgDiscovery and Safeguarding Natural Heritage Program: Strengthening Navajo Youth Connections to the Land.

Need and Use of the Information: To participate in these programs, applicants (students) must submit essays, letters of recommendation, and application packages. These applications are reviewed and rated by officials to select the program participants. In addition, cooperative agreements are used to facilitate the partnerships between APHIS and the participating universities to carry out these programs.

Description of Respondents: Individuals or households, public and

private universities, and state government.

Number of Respondents: 1,126.
Frequency of Responses: Reporting.
Total Burden Hours: 6,330.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–14672 Filed 7–8–21; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Tennessee 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 that the Tennessee Advisory Committee (Committee) will hold a meeting via web-conference on Thursday, July 15, 2021, at 12:00 p.m. Central Time. The purpose of the meeting is for the committee to discuss proposed civil rights topics of study.

DATES: The meetings will be held on:

- Thursday, July 15, 2021, at 12:00 p.m. Central Time—*https://civilrights.webex.com/civilrights/j.php?MTID=m992749f83df222cdaaa858ecac88662f* or Join by phone: 800–360–9505 USA Toll Free Access code: 1992 414 037

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. 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 conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Tennessee Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
III. Committee Discussion
IV. Next Steps
V. Public Comment
VI. Adjournment

Dated: July 6, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–14660 Filed 7–8–21; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–091]

Certain Steel Wheels (12–16.5 Inches Diameter) From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission in Part, and Intent To Rescind in Part; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain steel wheels (12–16.5 inches diameter) (certain steel wheels) from the People's Republic of China (China) during the February 25, 2019, through December 31, 2019, period of review (POR). Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5449.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2020, Commerce published a notice of opportunity to request administrative review of the countervailing duty (CVD) *Order* [1] covering the period February 25, 2019, through December 31, 2019.[2] Several interested parties requested that Commerce conduct an administrative review of the *Order* and, on February 6, 2021, Commerce published in the **Federal Register** a notice of initiation of an administrative review *Order* in relation to five parties.[3] On January 14, 2020, Commerce selected Xingmin Intelligent Transportation Systems (Group) and Zhejiang Jingu Company Limited (Zhejiang Jingu) as the mandatory respondents in this administrative review.[4]

Subsequent to Commerce's selection of mandatory respondents, the sole requests of the mandatory respondents were withdrawn.[5] On February 12, 2021, Commerce selected Xiamen Topu Imports & Export Co., Ltd (Xiamen Topu) as a replacement mandatory respondent, and on April 22, 2021, we selected Shanghai Yata Industry Company Limited (Shanghai Yata) as an additional mandatory respondent in this administrative review.[6] On May 6, 2021, Zhejiang Jingu and Shanghai Yata withdrew from participation in this administrative review.[7] On May 27,

[1] *See Certain Steel Trailer Wheels 12 to 16.5 Inches from the People's Republic of China: Antidumping Duty and Countervailing Duty Orders,* 84 FR 45952 (September 3, 2019) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 54349 (September 1, 2020).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68840 (October 30, 2020) (*Initiation Notice*).

[4] *See* Memorandum, ''Respondent Selection,'' dated January 14, 2021.

[5] *See* Trailstar's Letter, ''Withdrawal of Request for Administrative Review of the Countervailing Duty Order on Certain Steel Wheels 12 to 16.5 Inches in Diameter from the People Republic of China,'' dated January 28, 2021.

[6] *See* Memorandum, ''Respondent Selection: Selection of Replacement Mandatory Respondent,'' dated February 12, 2021; *see also* Memorandum, ''Respondent Selection: Selection of Replacement Mandatory Respondent,'' dated April 22, 2021.

[7] *See* Zhejiang Jingu's Letter, ''Notice Regarding Participation in Administrative Review,'' dated May 6, 2021. In the investigation, Commerce found that Shanghai Yata was affiliated through cross-ownership with Zhejiang Jingu. Commerce also determined that four other Chinese companies were cross-owned with Zhejiang Jingu: Shangdong Jingu Auto Parts Co., Ltd.; An'Gang Jingu (Hangzhou) Metal Materials Co., Ltd.; Zhejiang Wheel World Co., Ltd.; and Hangzhou Jingu New Energy Development Co. Ltd. *See Certain Steel Wheels 12 to 16.5 Inches in Diameter from the People's Republic of China: Final Affirmative Countervailing Duty Determination, and Final Affirmative Determination of Critical Circumstances,* 84 FR 32723 (July 9, 2019), and accompanying Issues and Decisions Memorandum.

2021, Commerce extended the deadline for the preliminary results of this review by 30 days.[8] Accordingly, the deadline for the preliminary results of this review was extended to July 2, 2021.

For events that occurred since the *Initiation Notice, see* the Preliminary Decision Memorandum.[9] A list of topics discussed in the Preliminary Decision Memorandum is included in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Order

The products covered by the *Order* are certain on-the-road steel wheels, discs, and rims for tubeless tires with a nominal wheel diameter of 12 inches to 16.5 inches, regardless of width. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). In reaching these preliminary results, Commerce relied on facts otherwise available, with the application of adverse inferences.[10] For further information, *see* ''Use of Facts Otherwise Available and Application of Adverse Inferences'' in the accompanying Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. We received a timely withdrawal of the requests for review, for which no other parties requested a review, for Xingmin Intelligent Transportation Systems (Group) (Xingmin Intelligent).[11] Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to this company.

Intent To Rescind Administrative Review, in Part

It is Commerce's practice to rescind an administrative review of a countervailing duty order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[12] Normally, upon completion of an administrative review, the suspended entries are liquidated at the countervailing duty assessment rate calculated for the review period.[13] Therefore, for an administrative review of a company to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the calculated countervailing duty assessment rate calculated for the review period.[14]

According to the CBP import data, one of the five companies subject to this review, Hangzhou Antego Industry Co. Ltd, which was not chosen as a mandatory respondent and for which its request for review was not withdrawn, did not have reviewable entries of subject merchandise during the POR for which liquidation is suspended. Accordingly, in the absence of reviewable, suspended entries of subject merchandise during the POR by Hangzhou Antego Industry Co. Ltd, we intend to rescind this administrative review, with respect to Hangzhou Antego Industry Co. Ltd, in accordance with 19 CFR 351.213(d)(3).

Use of Facts Otherwise Available and Application of Adverse Inferences

Subsequent to the initiation of this administrative review, Commerce issued initial questionnaires to the Government of China (GOC) dated January 21, 2021, February 16, 2021 and April 22, 2021, with a request for the GOC to forward the questionnaires to the respondents.[15] The GOC, Shanghai Yata, and Xiamen Topu failed to respond to the questionnaire by the specified deadlines. Therefore, because necessary information is not available on the record and because Shanghai Yata, Xiamen Topu, and the GOC failed to respond to Commerce's request for information, we preliminarily find that the use of facts available is warranted, pursuant to sections 776(a)(1) and 776(a)(2)(A), (B) and (C) of the Tariff Act of 1930, as amended (the Act). Moreover, because Shanghai Yata, Xiamen Topu, and the GOC did not cooperate to the best of their ability, pursuant to 776(b) of the Act, we preliminarily find that use of adverse facts available (AFA) is warranted to ensure that Shanghai Yata and Xiamen Topu do not obtain a more favorable result by failing to cooperate than if they had fully complied with our requests for information.

In the investigation, we determined that Shanghai Yata was cross-owned with Zhejiang Jingu during the periods of time relevant to the investigation.[16] Since the record of this administrative review contains no factual information that would lead Commerce to reconsider this cross-ownership determination, we preliminarily determine that Shanghai Yata remained cross-owned with Zhejiang Jingu during the POR. Accordingly, Zhejiang Jingu and its cross-owned companies, including Shanghai Yata are subject to the AFA

[8] *See* Memorandum, ''Extension of Deadline for the Preliminary Results of Countervailing Duty Administrative Review; 2019,'' dated May 27, 2021.

[9] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Certain Steel Wheels (12–16.5 inches diameter) from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[10] *See* section 776 of the Act.

[11] *See* TTT's Letter, ''Withdrawal of Request for Administrative Review of the Countervailing Duty Order on Certain Steel Wheels 12 to 16.5 Inches in Diameter from the People Republic of China,'' dated January 15, 2021.

[12] *See, e.g., Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015,* 82 FR 14349 (March 20, 2017); *see also Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019).

[13] *See* 19 CFR 351.212(b)(2).

[14] *See* 19 CFR 351.213(d)(3).

[15] *See* Commerce's Letter, ''Countervailing Duty Questionnaire,'' dated January 21, 2021 (Initial Questionnaire); *see also* Commerce's Letter, ''Selection of Replacement Mandatory Respondent,'' dated February 16, 2021; and Commerce's Letter, ''Selection of Additional Replacement Respondent,'' dated April 22, 2021. In its letter to the GOC, Commerce established the deadlines of March 2, 2021 for the Section III response identifying affiliated companies, and of March 25, 2021 for the remainder of Section III and the GOC's responses to the remainder of the Initial Questionnaire.

[16] *See Certain Steel Wheels 12 to 16.5 Inches in Diameter from the People's Republic of China: Final Affirmative Countervailing Duty Determination, and Final Affirmative Determination of Critical Circumstances,* 84 FR 32723 (July 9, 2019), and accompanying Issues and Decisions Memorandum (IDM). During the CVD investigation of certain steel wheels from China, Commerce determined that Zhejiang Jingu and Shanghai Yata were cross-owned companies. While the company that requested a review of Zhejiang Jingu withdrew its request for Zhejiang Jingu, Shanghai Yata remained in the administrative review because the company that filed a request for review of Shanghai Yata did not withdraw its request for review. Thus, because Shanghai Yata was still subject to the administrative review, we issued an initial questionnaire to Shanghai Yata. All cross-owned companies of Shanghai Yata were required to file a response to the questionnaire, including Zhejiang Jingu, if the companies remain cross-owned during the POR.

rate. For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.[17]

Preliminary Results of Review

Company	Net subsidy rate *ad valoreum* (percent)
Zhejiang Jingu Company Limited and Shanghai Yata Industry Company Limited[18]	388.31
Xiamen Topu Imports & Export Co., Ltd	388.31

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with the preliminary results of a review within ten days of its public announcement, or if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the three companies that remain in the administrative review, in accordance with section 776 of the Act, and because our calculation of the AFA subsidy rate is outlined in the Preliminary Decision Memorandum,[19] there are no further calculations to disclose.

Public Comment

Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[20] Rebuttals to case briefs may be filed no later than seven days after the case briefs are filed, and all rebuttal comments must be limited to comments raised in the case briefs.[21] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[22]

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the companies shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2) Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period February 25, 2019 through December 31, 2019, in accordance with 19 CFR 351.212(c)(l)(i).

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results are issued and published pursuant to sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 1, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Intent To Rescind Administrative Review, In Part
IV. Partial Rescission of Administrative Review
V. Scope of the Order
VI. Use of Facts Otherwise Available and Application of Adverse Inferences
  a. Legal Standard
  b. Application of AFA to the GOC and Non-Responsive Mandatory Respondents Shanghai Yata Xiamen Topu, and Zhejiang Jingu
  c. Selection of the AFA Rates
VII. Conclusion

[FR Doc. 2021–14638 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–DS–P

[17] *See* Preliminary Decision Memorandum at 5.

[18] In the investigation, we found that Zhejiang Jingu was cross-owned with An Gang Jingu (Hangzhou) Metal Materials Co., Ltd.; Hangzhou Jingu New Energy Development Co. Ltd.; Shangdong Jingu Auto Parts Co., Ltd.; Zhejiang Jingu Automobile Components; Zhejiang Wheel World Co., Ltd.; and Shanghai Yata Industry Company Limited. There is no information on the record of this administrative review that would lead Commerce to reconsider that determination, therefore, we preliminarily continue to find these companies cross-owned.

[19] *Id.*

[20] *See* 19 CFR 351.309(c).

[21] *See* 19 CFR 351.309(d).

[22] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 29615 (May 18, 2020); *and Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–020, C–570–021]

Melamine From the People's Republic of China: Continuation of Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) and the International Trade Commission (ITC) have determined that revocation of the antidumping duty (AD) and countervailing duty (CVD) orders on melamine from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping, net countervailable subsidies, and material injury to an industry in the United States. Therefore, Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Smith, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2181.

SUPPLEMENTARY INFORMATION:

Background

On December 28, 2015, Commerce published in the **Federal Register** the AD and CVD orders on melamine from

China.[1] On November 3, 2020, Commerce published the notice of initiation of the first sunset review of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On November 10, 2020, Commerce received notices of intent to participate from Cornerstone Chemical Company (Cornerstone, or domestic interested party), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] Cornerstone claimed interested party status under section 771(9)(C) of the Act, as a domestic producer engaged in the production of melamine in the United States.

On November 25, 2020, Commerce received substantive responses from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from any other domestic or interested parties and no hearing was requested.

On December 23, 2020, Commerce notified the ITC that it did not receive adequate substantive responses from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited (120-day) sunset reviews of these *Orders.*

As a result of its reviews, Commerce determined that revocation of the AD and CVD orders on melamine from China would likely lead to continuation or recurrence of dumping and subsidization. Therefore, Commerce notified the ITC of the magnitude of the margins likely to prevail should the orders be revoked, pursuant to sections 751(c)(1) and 752(b) and (c) of the Act.[6] On July 6, 2021, the ITC published its determinations, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[7]

Scope of the Orders

The merchandise subject to the *Orders* is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula $C_3H_6N_6$).[8] Melamine is a crystalline powder or granule typically (but not exclusively) used to manufacture melamine formaldehyde resins. All melamine is covered by the scope of these *Orders* irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of these *Orders.* Melamine that is otherwise subject to these orders is not excluded when commingled with melamine from sources not subject to these *Orders.* Only the subject component of such commingled products is covered by the scope of these *Orders.*

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to continuation or recurrence of dumping, countervailable subsidies, and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the AD and CVD orders on melamine from China. U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of continuation of these *Orders* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, Commerce intends to initiate the next five-year reviews of the *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: July 6, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–14640 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Melamine from the People's Republic of China: Antidumping Duty and Countervailing Duty Orders,* 80 FR 80751 (December 28, 2015) (*Orders*).

[2] *See Initiation of Five-Year ("Sunset") Reviews,* 85 FR 69585 (November 3, 2020).

[3] *See* Cornerstone's Letter, "Five-Year ('Sunset') Review Of Countervailing Duty Order On Melamine from the People's Republic Of China: Domestic Interested Party Notice of Intent to Participate," dated November 10, 2020; *see also* Cornerstone's Letter, "Five-Year ('Sunset') Review Of Antidumping Duty Order On Melamine from the People's Republic Of China: Domestic Interested Party Notice of Intent to Participate," dated November 10, 2020.

[4] *See* Cornerstone's Letter, "Five-Year ('Sunset') Review Of Countervailing Duty Order On Melamine from the People's Republic Of China: Domestic Interested Party Substantive Response," dated November 25, 2020; *see also* Cornerstone's Letter, "Five-Year ('Sunset') Review Of Antidumping Duty Order On Melamine from the People's Republic Of China: Domestic Interested Party Substantive Response," dated November 25, 2020.

[5] *See* Commerce's Letter, "Sunset Reviews for November 2020," dated December 23, 2020.

[6] *See Melamine from the People's Republic of China: Final Results of the Expedited Five-Year Sunset Review of the Countervailing Duty Order,* 86 FR 11501 (February 25, 2021); *see also Melamine from the People's Republic of China: Final Results of the Expedited Five-Year Sunset Review of the Antidumping Duty Order,* 86 FR 13528 (March 9, 2021).

[7] *See Melamine from China,* 86 FR 35531 (July 6, 2021).

[8] Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–898]

Chlorinated Isocyanurates From the People's Republic of China: Final Determination of No Shipments; 2019–2020 Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that Heze Huayi Chemical Co., Ltd. (Heze Huayi) and Juancheng Kangtai Chemical Co., Ltd. (Kangtai) did not have any shipments of subject merchandise during the period of review (POR) June 1, 2019, through May 31, 2020.

DATES: Applicable July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3964.

SUPPLEMENTARY INFORMATION:

Background

On March 8, 2021, Commerce published its *Preliminary Results* of the administrative review of the antidumping duty order on chlorinated isocyanurates (chlorinated isos) from China covering the period June 1, 2019,

through May 31, 2020.[1] The petitioners in this investigation are Bio-lab, Inc., Clearon Corp., and Occidental Chemical Corp. (collectively, the petitioners). The mandatory respondents in this administrative review are Heze Huayi and Kangtai. No case or rebuttal briefs for this review were submitted by the parties.

On September 8, 2020, Heze Huayi and Kangtai both certified that their respective companies had no entries of subject merchandise during the POR.[2] On November 17, 2020, our review of U.S. Customs and Border Protection (CBP) data indicated that Heze Huayi and Kangtai had no entries of subject merchandise originating from China, that were subject to antidumping duties during the POR.[3] On May 19, 2021, Commerce issued a no shipment inquiry to CBP with respect to Heze Huayi and Kangtai.[4] On May 24, 2021, CBP responded that it has no record of any subject entries for this inquiry.[5]

Scope of the Order

The products covered by the order are chlorinated isos, which are derivatives of cyanuric acid, described as chlorinated s-triazine triones. For a full description of the scope of the order, *see* Preliminary Decision Memorandum.[6]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213.

Final Determination of No Shipments

In the *Preliminary Results,* we found that Heze Huayi and Kangtai had no entries of subject merchandise during the POR.[7] No parties commented on, nor did we receive information that contradicts this preliminary determination. Therefore, for the final results, we continue to find that Heze Huayi and Kangtai had no reviewable entries during the POR. Consistent with our assessment practice in non-market economy administrative reviews, Commerce did not rescind this review for Heze Huayi and Kangtai but completed the review and will issue appropriate instructions to CBP based on these final results.[8]

China-Wide Entity

Pursuant to Commerce's policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity.[9] Because no party requested a review of the China-wide entity, we did not review the entity in this segment of the proceeding. Thus, the China-wide entity's rate (*i.e.,* 285.63 percent) did not change.

Assessment Rates

Pursuant to Commerce's assessment practice, if Commerce determines that an exporter had no shipments of the subject merchandise, we intend to issue liquidation instructions for any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) and to liquidate at the China-wide entity rate.[10]

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Consistent with its recent notice,[11] Commerce intends to issue appropriate assessment instructions directly to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For Heze Huayi and Kangtai, the cash deposit rate will continue to be the existing producer/exporter-specific rate published for the most recent period; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be the existing producer/exporter-specific rate published for the most recent period; (3) for all Chinese exporters of subject merchandise that have not been found to be eligible for a separate rate, the cash deposit rate will be the China-wide rate of 285.63 percent; and (4) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and that subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to

[1] *See Chlorinated Isocyanurates from the People's Republic of China: Preliminary Determination of No Shipments; 2019–2020,* 86 FR 13291 (March 8, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Heze Huayi's Letter, ''Chlorinated Isocyanurates from the People's Republic of China: No Sales Certification,'' dated September 8, 2020; *see also* Kangtai's Letter, ''Chlorinated Isocyanurates from the People's Republic of China: No Sales Certification,'' dated September 8, 2020.

[3] *See* Memorandum, ''U.S. Customs and Border Protection (CBP) Data for Heze Huayi Chemical Co., Ltd. and Juancheng Kangtai Chemical Co., Ltd.,'' dated November 17, 2020.

[4] CBP message 1139404, dated May 19, 2021.

[5] *See* Memorandum, ''Chlorinated Isocyanurates from the People's Republic of China; No Shipment Inquiry for Heze Huayi Chemical Co., Ltd. and Juancheng Kangtai Chemical Co., Ltd. during the period 06/01/2019 through 05/31/2020,'' dated May 25, 2021.

[6] *See Preliminary Results* PDM at 2.

[7] *See Preliminary Results,* 86 FR 13291–13292.

[8] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011); *see also* the ''Assessment Rates' '' section, below.

[9] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[10] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011). For an explanation on the derivation of the China-wide rate, *see Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates from the People's Republic of China,* 70 FR 24502, 24505 (May 10, 2005).

[11] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 3995 (January 15, 2021).

judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h).

Dated: July 2, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–14639 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–896]

Magnesium Metal From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to find that Tianjin Magnesium International, Co., Ltd. (TMI) and Tianjin Magnesium Metal, Co., Ltd. (TMM) had no shipments of subject merchandise covered by the antidumping duty order on magnesium metal from the People's Republic of China (China) for the period of review (POR) April 1, 2019, through May 31, 2020.

DATES: Applicable July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5449.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2021, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register**.[1] No interested party submitted comments concerning the *Preliminary Results* or requested a hearing in this administrative review. Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). The current deadline for these final results is July 2, 2021.

Scope of the Order[2]

The product covered by the *Order* is magnesium metal from China, which includes primary and secondary alloy magnesium metal, regardless of chemistry, raw material source, form, shape, or size. Magnesium is a metal or alloy containing by weight primarily the element magnesium. Primary magnesium is produced by decomposing raw materials into magnesium metal. Secondary magnesium is produced by recycling magnesium-based scrap into magnesium metal. The magnesium covered by the *Order* includes blends of primary and secondary magnesium. The subject merchandise includes the following alloy magnesium metal products made from primary and/or secondary magnesium including, without limitation, magnesium cast into ingots, slabs, rounds, billets, and other shapes; magnesium ground, chipped, crushed, or machined into rasping, granules, turnings, chips, powder, briquettes, and other shapes; and products that contain 50 percent or greater, but less than 99.8 percent, magnesium, by weight, and that have been entered into the United States as conforming to an ''ASTM Specification for Magnesium Alloy''[3] and are thus outside the scope of the existing antidumping orders on magnesium from China (generally referred to as ''alloy'' magnesium).

The scope of the *Order* excludes: (1) All forms of pure magnesium, including chemical combinations of magnesium and other material(s) in which the pure magnesium content is 50 percent or greater, but less than 99.8 percent, by weight, that do not conform to an ''ASTM Specification for Magnesium Alloy;''[4] (2) magnesium that is in liquid or molten form; and (3) mixtures containing 90 percent or less magnesium in granular or powder form by weight and one or more of certain non-magnesium granular materials to make magnesium-based reagent mixtures, including lime, calcium metal, calcium silicon, calcium carbide, calcium carbonate, carbon, slag coagulants, fluorspar, nephaline syenite, feldspar, alumina (Al203), calcium aluminate, soda ash, hydrocarbons, graphite, coke, silicon, rare earth metals/mischmetal, cryolite, silica/fly ash, magnesium oxide, periclase, ferroalloys, dolomite lime, and colemanite.[5] The merchandise subject to this *Order* is classifiable under items 8104.19.00, and 8104.30.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined TMI and TMM had no shipments of subject merchandise to the United States during the POR.[6] As noted in the *Preliminary Results,* we received no-shipment statements from TMI and TMM, and the statements were consistent with the information we received from U.S. Customs and Border Protection (CBP).[7] Because Commerce did not receive any comments on its preliminary finding, Commerce continues to find that TMI and TMM did not have any shipments of subject merchandise during the POR.

Assessment Rates

We have not calculated any assessment rates in this administrative review. Based on record evidence, we have determined that TMI and TMM

[1] *See Magnesium Metal from the People's Republic of China: Preliminary Results of Antidumping Administrative Review; 2019–20,* 86 FR 12621 (March 4, 2021) (*Preliminary Results*).

[2] *See Notice of Antidumping Duty Order: Magnesium Metal from the People's Republic of China,* 70 FR 19928 (April 15, 2005) (*Order*).

[3] The meaning of this term is the same as that used by the American Society for Testing and Materials in its Annual Book for ASTM Standards: Volume 01.02 Aluminum and Magnesium Alloys.

[4] The material is already covered by existing antidumping orders. *See Notice of Antidumping Duty Orders: Pure Magnesium from the People's Republic of China, the Russian Federation and Ukraine; Notice of Amended Final Determination of Sales at Less Than Fair Value: Antidumping Duty Investigation of Pure Magnesium from the Russian Federation,* 60 FR 25691 (May 12, 1995); and *Antidumping Duty Order: Pure Magnesium in Granular Form from the People's Republic of China,* 66 FR 57936 (November 19, 2001).

[5] This third exclusion for magnesium-based reagent mixtures is based on the exclusion for reagent mixtures in the 2000–2001 investigations of magnesium from China, Israel, and Russia. *See Final Determination of Sales at Less Than Fair Value: Pure Magnesium in Granular Form from the People's Republic of China,* 66 FR 49345 (September 27, 2001); *see also Final Determination of Sales at Less Than Fair Value: Pure Magnesium from Israel,* 66 FR 49349 (September 27, 2001); and *Final Determination of Sales at Not Less Than Fair Value: Pure Magnesium from the Russian Federation,* 66 FR 49347 (September 27, 2001). These mixtures are not magnesium alloys, because they are not combined in liquid form and cast into the same ingot.

[6] *See Preliminary Results,* 86 FR at 12622.

[7] *See* Memorandum, ''Correction of February 2, 2021 Memorandum Placing CBP Data on the Record,'' dated February 3, 2021; *see also* Memorandum, ''Magnesium Metal from China; No Shipment Inquiry for Tianjin Magnesium International Co., Ltd and Tianjin Magnesium Metal Co., Ltd. during the period 04/01/2019 through 03/31/2020,'' dated February 24, 2021. On February 5, 2021, Commerce issued a no shipment inquiry to CBP with respect to TMI and TMM. On February 18, 2021, CBP responded that it had no evidence of shipments of magnesium metal from China exported by TMI and TMM during the POR.

had no shipments of subject merchandise during the POR, and, therefore, pursuant to Commerce's assessment practice, any suspended entries entered under their case numbers will be liquidated at the China-wide entity rate.[8]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed Chinese and non-Chinese exporters that received a separate rate in a prior segment of this proceeding, including TMI, the cash deposit rate will continue to be the existing exporter-specific rate; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, including TMM, the cash deposit rate will be the China-wide rate of 141.49 percent; [9] and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protection Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return of destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a) and 777(i) of the Act, and 19 CFR 351.213(h).

Dated: July 1, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–14641 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[9] *See Order.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB220]

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit amendments.

SUMMARY: Notice is hereby given that permits and permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Sara Young (Permit No. 24365), Amy Hapeman (Permit No. 18890–01), and Jennifer Skidmore (Permit No. 25672); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the activities, go to *www.federalregister.gov* and search on the permit number provided in Table 1 below.

TABLE 1—ISSUED PERMITS AND PERMIT AMENDMENTS

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
18890–01	0648–XD824	Alaska Department of Fish and Game, 1255 West 8th Street, Juneau, Alaska 99811–5526, (Responsible Party: Lori Quakenbush).	81 FR 59982; August 31, 2016	June 7, 2021.
23896	0648–XA964	Aleut Community of St. Paul Island, Tribal Government Ecosystem Conservation Office, 2050 Venia Minor Road, St. Paul Island, AK 99660 (Responsible Party: Lauren Divine, Ph.D.).	86 FR 16588; March 30, 2021	June 22, 2021.
24365	0648–XA878	Paul Ponganis, Ph.D., University of California San Diego, La Jolla, CA 92093–0204.	86 FR 11730; February 26, 2021	June 1, 2021.
25672	0648–XB073	Miling Li, Sc.D., University of Delaware, 15 Innovation Way, Newark, DE 19711.	86 FR 26209; May 13, 2021	June 22, 2021.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to

prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: July 6, 2021.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–14658 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB207]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Scientific and Statistical Committee (SSC) via webinar. See **SUPPLEMENTARY INFORMATION**.

DATES: The SSC meeting will take place July 28, 2021, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held via webinar.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public via webinar as it occurs. Webinar registration is required. Information regarding webinar registration will be posted to the Council's website at: *http://safmc.net/safmc-meetings/scientific-and-statistical-committee-meetings/* as it becomes available. The meeting agenda, briefing book materials, and online comment form will be posted to the Council's website two weeks prior to the meeting. Written comment on SSC agenda topics is to be distributed to the Committee through the Council office, similar to all other briefing materials. For this meeting, the deadline for submission of written comment is 5 p.m. July 28, 2021.

Agenda Items

The SSC will review projections from the SEDAR (Southeast Data Assessment and Review) 73 South Atlantic Red Snapper stock assessment and provide fishing level recommendations; provide comments on a National Marine Fisheries Service draft technical memo entitled ''Managing the Annual Catch Limits (ACLs) for data-limited stocks in federal fishery management plans''; and develop a workplan and workgroup for catch level projections best practices for stocks assessed in the South Atlantic region. The SSC will provide guidance to staff and make recommendations for Council consideration as appropriate.

Multiple opportunities for comment on agenda items will be provided during SSC meetings. Open comment periods will be provided at the start of the meeting and near the conclusion. Those interested in providing comment should indicate such in the manner requested by the Chair, who will then recognize individuals to provide comment. Additional opportunities for comment on specific agenda items will be provided, as each item is discussed, between initial presentations and SSC discussion. Those interested in providing comment should indicate such in the manner requested by the Chair, who will then recognize individuals to provide comment. All comments are part of the record of the meeting.

Although non-emergency issues not contained in the meeting agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least (5) business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 2, 2021.

Diane M. DeJames-Daly,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–14604 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2021–0032]

Patent Eligibility Jurisprudence Study

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for information.

SUMMARY: At the request of Senators Tillis, Hirono, Cotton, and Coons, the United States Patent and Trademark Office (USPTO) is undertaking a study on the current state of patent eligibility jurisprudence in the United States, and how the current jurisprudence has impacted investment and innovation, particularly in critical technologies like quantum computing, artificial intelligence, precision medicine, diagnostic methods, and pharmaceutical treatments. The USPTO seeks public input on these matters to assist in preparing the study.

DATES: Comments must be received by September 7, 2021.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via the portal, enter docket number PTO–P–2021–0032 on the homepage and click ''Search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for information and click on the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because

comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included.

Visit the Federal eRulemaking Portal (*www.regulations.gov*) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions on how to submit comments by other means.

Submissions of Business Confidential Information: Any submissions containing business confidential information must be marked ''confidential treatment requested'' and submitted through *www.regulations.gov.* Submitters should provide an index listing the document(s) or information they would like the USPTO to withhold. The index should identify the confidential document(s) by document number(s) and document title(s) and should identify the confidential information by description(s) and relevant page numbers and/or section numbers within a document. Submitters should also provide a statement explaining their grounds for requesting non-disclosure of the information to the public. The USPTO also requests that submitters of business confidential information include a non-confidential version (either redacted or summarized) that will be posted on *www.regulations.gov* and available for public viewing. In the event that the submitter cannot provide a non-confidential version of their submission, the USPTO requests that the submitter post a notice in the docket stating that they have provided the USPTO with business confidential information. Should a submitter fail either to docket a non-confidential version of their submission or to post a notice that business confidential information has been provided, the USPTO will note the receipt of the submission on the docket with the submitter's organization or name (to the degree permitted by law) and the date of submission.

Anonymous submissions: The USPTO will accept anonymous submissions. Enter ''N/A'' in the required fields if you wish to remain anonymous.

FOR FURTHER INFORMATION CONTACT: Elizabeth Shaw, USPTO, Office of Policy and International Affairs, at *Elizabeth.Shaw2@uspto.gov* or 571–272–9300. Please direct media inquiries to the USPTO's Office of the Chief Communications Officer at 571–272–8400.

SUPPLEMENTARY INFORMATION: In 2016, following the Supreme Court's decisions in *Bilski,*[1] *Mayo,*[2] *Myriad,*[3] and *Alice,*[4] the USPTO held two public roundtables and invited written comments from the public on the state of the law of patent subject matter eligibility and the Court's legal framework for evaluating eligibility. Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, 81 FR 71485 (Oct. 17, 2016). The first roundtable focused on the then-current USPTO eligibility guidance for patent examiners. *Id.* at 71487.[5] The second roundtable explored the legal contours of patent eligibility, including the impact of the current law, if/how the law should be revised, and whether a legislative solution should be sought. *Id.* at 71486–71487. In July 2017, the USPTO published a report summarizing patent eligibility law, public views on the impact of the recent Supreme Court patent eligibility jurisprudence, and public recommendations for a path forward. USPTO, Patent Eligible Subject Matter: Report on Views and Recommendations from the Public (July 2017), available at *www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf.*

Since 2017, the Federal Circuit has issued numerous decisions applying the Supreme Court's legal framework in a variety of contexts, and many petitions for writ of certiorari have been filed. In 2019, the Supreme Court called for the views of the Solicitor General. *HP Inc.* v. *Berkheimer,* No. 18–415, 139 S. Ct. 860 (Jan. 7, 2019); *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.,* No. 18–817, 139 S. Ct. 1368 (Mar. 18, 2019). In both cases, the Government argued that the Court's recent decisions have strayed from earlier precedent and have fostered uncertainty regarding the patent eligibility standards. Brief for United States, *HP Inc.* v. *Berkheimer,* No. 18–415, 2019 WL 6715368, at *10–13 (Dec. 6, 2019) (Berkheimer CVSG Brief); Brief for United States, *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.,* No. 18–817, 2019 WL 6699397, at *13–21 (Dec. 6, 2019) (Vanda CVSG Brief). While the Government contended that neither of the cases was an optimal vehicle to consider those standards, it urged the Court to grant certiorari in an appropriate case. Berkheimer CVSG Brief at *10, *14, *19; Vanda CVSG Brief at *8, *22–23. In particular, the Government highlighted the then-pending certiorari petition in *Athena Diagnostics, Inc.* v. *Mayo Collaborative Services, LLC,* a case involving medical diagnostic methods in which the Federal Circuit, in denying rehearing en banc, issued multiple separate opinions asking the Supreme Court for further guidance in the area. Berkheimer CVSG Brief at *13, *19; Vanda CVSG Brief at *22–23. Ultimately, the Supreme Court denied writ of certiorari in all three cases. *HP Inc.* v. *Berkheimer,* No. 18–415, 140 S. Ct. 911 (Jan. 13, 2020); *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.,* No. 18–817, 140 S. Ct. 911 (Jan. 13, 2020); *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC,* No. 19–430, 140 S. Ct. 855 (Jan. 13, 2020).

Last year, after a split panel decision concluding that a method for manufacturing drive shafts was patent ineligible, the Federal Circuit again issued a decision denying rehearing en banc that included multiple separate opinions with differing views on the scope of patent eligible subject matter. *Am. Axle & Mfg., Inc.* v. *Neapco Holdings LLC,* 966 F.3d 1347 (Fed. Cir. 2020). Like the dissenting judge on the panel, several of the opinions denying rehearing en banc faulted the panel majority for establishing a new ''nothing more'' test—if the claimed invention ''clearly invokes a natural law, and nothing more, to accomplish a desired result''—for patent ineligibility. *Id.* at 1366 (O'Malley J., dissenting); *id.* at 1361 (Stoll J., dissenting); *id.* at 1359 (Newman J., dissenting). American Axle petitioned for writ of certiorari on December 28, 2020, and the Supreme Court called for the views of the Solicitor General on May 3, 2021. *Am. Axle & Mfg., Inc.* v. *Neapco Holdings LLC,* No. 20–891, 2021 WL 1725166 (May 3, 2021). The questions presented in the petition are: (1) What is the appropriate standard for determining whether a claim is directed to a patent-ineligible concept under step one of the *Alice* two-step framework?; and (2) Is patent eligibility a question of law for the court or a question of fact for the jury?

On March 5, 2021, Senators Thom Tillis, Mazie Hirono, Tom Cotton, and Christopher Coons sent a letter to Mr. Drew Hirshfeld, Performing the functions and duties of the Director of the USPTO, asking that the USPTO

[1] *Bilski* v. *Kappos,* 561 U.S. 593 (2010).

[2] *Mayo Collaborative Servs.* v. *Prometheus Labs., Inc.,* 566 U.S. 66 (2012).

[3] *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.,* 569 U.S. 576 (2013).

[4] *Alice Corp.* v. *CLS Bank Int'l,* 573 U.S. 208 (2014).

[5] The USPTO issued revised patent subject matter eligibility guidance for examiners in 2019. USPTO, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 FR 50 (Jan. 7, 2019); USPTO, October 2019 Patent Eligibility Guidance Update, 84 FR 55942–55943 (Oct. 18, 2019). That guidance has since been incorporated into the Manual of Patent Examining Procedure, sections 2103 to 2106.07(c) (9th ed., rev. 10.2019) (June 2020). *See www.uspto.gov/PatentEligibility.*

publish a request for information on the current state of patent eligibility jurisprudence in the United States (since the Supreme Court's decisions in *Mayo* and *Alice*), evaluate the responses, and provide a detailed summary of its findings by March 5, 2022. The Senators indicated a particular interest in learning how the current jurisprudence has adversely impacted investment and innovation in critical technologies like quantum computing, artificial intelligence,[6] precision medicine, diagnostic methods, and pharmaceutical treatments.

Request for Information: To aid in the study that Senators Tillis, Hirono, Cotton, and Coons requested, the USPTO invites stakeholders to submit written comments on the questions below. In the questions, the phrase ''the current state of patent eligibility jurisprudence in the United States'' should be understood as referring to the body of patent subject matter eligibility decisions issued by the U.S. Federal Judiciary.

When responding to the questions, please identify yourself and your interest in the U.S. patent system. If applicable, please indicate whether you fall within one or more of the following categories: (1) Inventors, patent owners, or investors (*e.g.,* venture capital, investment bank, fund, etc.); (2) licensees or users of patented technology; (3) entities that represent inventors or patent owners (*e.g.,* law firms); (4) recipients of demand letters concerning alleged patent infringement or accused infringers in a patent lawsuit; (5) entities that represent accused infringers; (6) government agencies or officials; (7) academic or research institutions; (8) intellectual property organizations or associations; and (9) nonprofit organizations or advocacy groups. Additionally, if you are a patent owner or inventor, please include the number of U.S. and foreign patent applications you have filed; the number of U.S. and foreign patents you hold; the number of patents you have licensed or sold; and the number of patent cases you have been involved in since the Supreme Court's decision in *Bilski* in 2010.

Commenters need not respond to every question and may provide relevant information even if not responsive to a particular question.

Topics for Public Comment

Section I—Observations and Experiences

1. Please explain how the current state of patent eligibility jurisprudence affects the conduct of business in your technology area(s). Please identify the technology area(s) in your response.

2. Please explain what impacts, if any, you have experienced as a result of the current state of patent eligibility jurisprudence in the United States. Please include impacts on as many of the following areas as you can, identifying concrete examples and supporting facts when possible:

a. Patent prosecution strategy and portfolio management;
b. patent enforcement and litigation;
c. patent counseling and opinions;
d. research and development;
e. employment;
f. procurement;
g. marketing;
h. ability to obtain financing from investors or financial institutions;
i. investment strategy;
j. licensing of patents and patent applications;
k. product development;
l. sales, including downstream and upstream sales;
m. innovation; and
n. competition.

3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas:

a. Quantum computing;
b. artificial intelligence;
c. precision medicine;
d. diagnostic methods;
e. pharmaceutical treatments; and
f. other computer-related inventions (*e.g.,* software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

4. Please explain how your experiences with the application of subject matter eligibility requirements in other jurisdictions, including China, Japan, Korea, and Europe, differ from your experiences in the United States.

5. Please identify instances where you have been denied patent protection for an invention in the United States solely on the basis of patent subject matter ineligibility, but obtained protection for the same invention in a foreign jurisdiction, or vice versa. Please provide specific examples, such as the technology(ies) and jurisdiction(s) involved, and the reason the invention was held ineligible in the United States or other jurisdiction.

6. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to modify or shift investment, research and development activities, or jobs from the United States to other jurisdictions, or to the United States from other jurisdictions. If so, please identify the relevant modifications and their associated impacts.

7. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to change business strategies for protecting your intellectual property (*e.g.,* shifting from patents to trade secrets, or vice versa). If so, please identify the changes and their associated impacts.

8. Please explain whether you have changed your behavior with regard to filing, purchasing, licensing, selling, or maintaining patent applications and patents in the United States as a result of the current state of patent eligibility jurisprudence in the United States. If so, please describe how you changed your behavior.

9. Please explain how, in your experience, the status of patent eligibility jurisprudence in the United States has affected any litigation for patent infringement in the United States in which you been involved as a party, as legal counsel, or as another participant (*e.g.,* an expert witness). For example, please explain whether this jurisprudence has affected the cost or duration of such litigation, the ability to defend against claims of patent infringement, the certainty/uncertainty of litigation outcomes, or the likelihood of settlement.

Section II—Impact of Subject Matter Eligibility on the General Marketplace

10. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property.

11. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the U.S. economy as a whole.

12. Please identify how the current state of subject matter eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property and the U.S. economy in any of the following areas:

a. Quantum computing;
b. artificial intelligence;
c. precision medicine;
d. diagnostic methods;
e. pharmaceutical treatments; and
f. other computer-related inventions (*e.g.,* software, business methods,

[6] On October 6, 2020, the USPTO released a report titled ''Public Views on Artificial Intelligence and Intellectual Property Policy.'' The report takes a comprehensive look at a wide variety of stakeholder views on the impact of artificial intelligence across the intellectual property landscape. *See generally* ''Public Views on Artificial Intelligence and Intellectual Property Policy,'' available at *www.uspto.gov/sites/default/files/documents/USPTO_AI-Report_2020-10-07.pdf.*

computer security, databases and data structures, computer networking, and graphical user interfaces).

In responding to this question, please provide concrete examples and supporting facts when possible.

13. Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?

Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2021–14628 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) and service(s) previously furnished by such agencies.

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

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Service Type: Fourth-Party Logistics (4PL) of Personal Protective Equipment Safety Stock
Mandatory for: Department of Homeland Security, Departmental Operations Acquisition Division
Designated y Source of Supply: National Industries for the Blind, Alexandria, VA
Contracting Activity: Department of Homeland Security, Departmental Operations Acquisition Division

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7520–01–383–7929—Marker, Tube Type, Highlighter, Chisel Tip, Magenta
Designated Source of Supply: Dallas Lighthouse for the Blind, Inc., Dallas, TX
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Service(s)

Service Type: Document Destruction
Mandatory for: Defense Logistics Agency, Defense Supply Center, Columbus, OH, 3990 East Broad Street, Columbus, OH
Mandatory Source of Supply: Greene, Inc., Xenia, OH
Contracting Activity: DEFENSE LOGISTICS AGENCY, DCSO COLUMBUS

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2021–14635 Filed 7–8–21; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* August 8, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 6/4/2021, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7930–00–NIB–0213—Finish Remover, Concentrate, 2 Liter
Designated Source of Supply: Beacon Lighthouse, Inc., Wichita Falls, TX
Contracting Activity: STRATEGIC ACQUISITION CENTER, FREDERICKSBURG, VA

NSN(s)—Product Name(s):
7520–01–618–9917—Portable Desktop Clipboard, 9½″ W x 1½″ D x 13½″ H, Black
7520–01–653–5889—Clipboard, Desktop, Reflective Yellow, 9½″ W x 1½″ D x 13½″ H
Designated Source of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: GSA/FAS ADMIN

SVCS ACQUISITION BR (2, NEW YORK, NY

NSN(s)—Product Name(s): 8465–01–524–7253—Adapter, ALICE Clip, Universal Camouflage

Designated Source of Supply: Lions Services, Inc., Charlotte, NC

Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s): MR 11319—Mug, Travel, Stainless Steel, Classic, 20 oz.

Designated Source of Supply: Association for Vision Rehabilitation and Employment, Inc., Binghamton, NY

Contracting Activity: Military Resale-Defense Commissary Agency

NSN(s)—Product Name(s): 7930–01–513–9968—Remover, Carpet Stain, Aerosol, 19 oz

Designated Source of Supply: The Lighthouse for the Blind, St. Louis, MO

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

Service(s)

Service Type: Temp. Admin./General Support Services

Mandatory for: GSA, Southwest Supply Center: 819 Taylor Street, Fort Worth, TX

Designated Source of Supply: Tarrant County Association for the Blind, Fort Worth, TX

Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR

Service Type: Administrative/General Support Services

Mandatory for: GSA, Southwest Supply Center: 819 Taylor Street, Fort Worth, TX

Designated Source of Supply: Louisiana Association for the Blind, Shreveport, LA

Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR

Service Type: Shelf Stocking, Custodial & Warehousing

Mandatory for: Fort Knox, Fort Knox, KY

Contracting Activity: DEFENSE COMMISSARY AGENCY (DECA), DEFENSE COMMISSARY AGENCY

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2021–14634 Filed 7–8–21; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0060]

Privacy Act of 1974; Matching Program

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Notice of a new matching program.

SUMMARY: This Computer Matching Agreement (CMA) verifies the eligibility of Military Health System (MHS) beneficiaries who are Medicare eligible to receive TRICARE Benefits.

DATES: Comments will be accepted on or before August 9, 2021. This proposed action will be effective the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Director of Administration and Management, Directorate of Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl D. Jenkins, Management Analyst, Defense Privacy, Civil Liberties, and Transparency Division at (703) 571–0070.

SUPPLEMENTARY INFORMATION: The DoD, Defense Manpower Data Center (DMDC) will provide the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) a list of specific data elements for all DoD eligible beneficiaries both over and under the age of 65. CMS will: (1) Match the Social Security Numbers (SSNs) of beneficiaries provided by DMDC against the information found in CMS's ''Enrollment Database (EDB)'' system of records; (2) validate the identification of the beneficiary and provide the Health Insurance Claim Number (HICN) to match against the SSN and date of birth provided by DMDC; (3) also provide the Medicare enrollment status and address of the beneficiary in the response file to DMDC. After receipt of the response file from CMS, DMDC will update the Defense Enrollment Eligibility Reporting System (DEERS) with appropriate Medicare information provided in the response file. The verified identification of eligible beneficiaries and their current Medicare enrollment status is maintained in DEERS for use by the Defense Health Agency in the management of its programs.

Participating Agencies: The Department of Defense, Defense Manpower Data Center, and the Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Authority for Conducting the Matching Program: 10 U.S.C. 1086(d).

Purpose(s): This matching program verifies the eligibility of MHS beneficiaries who are Medicare eligible to receive TRICARE benefits.

Categories of Individuals: The categories of individuals whose information is involved in the matching program is all members and retirees of the DoD and all of the Uniformed Services, and DoD beneficiaries (*e.g.,* dependent family members, legal guardians and other protectors and prior military members eligible for Department of Veterans Affairs benefits).

Categories of Records: The categories of records involved in the matching program are SSN, date of birth, gender, DEERs Benefits Number, and Medicare eligibility and enrollment data. DMDC will provide CMS with a finder file for the Under and Over 65 Populations to match against an assigned CMS HICN or Medicare Beneficiary Identifier (MBI) which are contained within EDB. The finder file sent from DoD will contain SSN, date of birth, sex code, and first and last name. The finder file will be used for SSN matching against an assigned HICN or MBI number. CMS will provide DoD with a reply file which will contain SSN, date of birth, sex code, first name, last name, and Medicare data. DMDC will provide data for approximately 10 million beneficiaries from DEERS to CMS for matching on a weekly basis. CMS will provide a reply file containing all appropriate matched and failed responses.

System of Records: ''Defense Enrollment Eligibility Reporting System (DEERS),'' DMDC 02 DoD, published in full at 84 FR 55293 (October 16, 2019), and updated at 84 FR 65975 (December 2, 2019). ''Military Health Information System (MHIS),'' EDHA 07, published at 85 FR 36190 (June 15, 2020). ''Enrollment Database (EDB),'' 09–70–0502, published in full at 73 FR 10249 (February 26, 2008), updated at 78 FR 23938 (April 23, 2013), 81 FR 8204 (February 18, 2016), and 83 FR 6591 (February 14, 2018).

Dated: July 6, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–14646 Filed 7–8–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Teacher and School Leader Incentive Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2021 for the Teacher and School Leader Incentive Program (TSL), Assistance Listing Number 84.374A. This notice relates to the approved information collection under OMB control number 1810–0758.

DATES:

Applications available: July 9, 2021.

Pre-application webinars: The Office of Elementary and Secondary Education intends to post pre-recorded informational webinars designed to provide technical assistance to interested applicants for TSL grants. These informational webinars will be available on the TSL web page shortly after this notice is published in the **Federal Register**.

Deadline for optional notice of intent to apply: July 30, 2021.

Deadline for transmittal of applications: August 13, 2021.

Deadline for intergovernmental review: October 12, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/FR-2019-02-13/pdf/2019-02206.pdf.*

The informational webinars will be available on the TSL web page at *oese.ed.gov/offices/office-of-discretionary-grants-support-services/effective-educator-development-programs/teacher-and-school-leader-incentive-program/applicant-info-eligibility/.* A TSL Frequently Asked Questions document will also be published on the TSL program web page as soon as it is available at *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/effective-educator-development-programs/teacher-and-school-leader-incentive-program/.*

FOR FURTHER INFORMATION CONTACT: Orman Feres, U.S. Department of Education, 400 Maryland Avenue SW, Room 3C140, Washington, DC 20202–5960. Telephone: (202) 453–6921. Email: *orman.feres@ed.gov* or *TSL@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:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of TSL is to assist States, local educational agencies (LEAs), and nonprofit organizations to develop, implement, improve, or expand comprehensive Performance-Based Compensation Systems (PBCS) [1] or Human Capital Management Systems (HCMS) for teachers, principals, and other School Leaders (educators) (especially for educators in High-Need Schools who raise student growth and academic achievement and close the achievement gap between high- and low-performing students). In addition, a portion of TSL funds may be used to study the effectiveness, fairness, quality, consistency, and reliability of PBCS or HCMS for educators.

Background: TSL is authorized under section 2212 of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA).

The FY 2021 TSL competition is designed to support entities in implementing, improving, or expanding their HCMS, which by definition must include a PBCS, or implementing, improving, or expanding only a PBCS. Absolute Priority 1 is consistent with this purpose. TSL is also intended to primarily serve educators in High-Need Schools who raise student academic achievement and close the achievement gap between high- and low-performing students, although the program may also fund services for educators serving in high-need subject areas (though not necessarily in High-Need Schools), as determined by the LEA or the State.

It is well established that teacher effectiveness contributes greatly to student academic outcomes, yet there is variation in teacher effectiveness within and across schools, including significant inequity in students' access to effective teachers, particularly for students from low-income backgrounds, students of color, English learners, and students with disabilities. As such, it is essential to attract and retain a well-qualified, experienced, effective, and diverse pool of skilled educators who are prepared to teach diverse learners (*e.g.,* through co-teaching models, dual certifications, universal design for learning), particularly in High-Need Schools.

Many States and LEAs have worked to create and improve their comprehensive HCMS, and LEAs have invested in high-quality educator evaluation and support systems in order to improve recruitment and retention efforts, provide educators with meaningful feedback and targeted Evidence-Based professional development, and use information across multiple indicators of educator performance to inform key school- and district-level decisions. In contrast to earlier Teacher Incentive Fund (TIF) competitions, the Department, in the 2017 and 2020 TSL competitions, as well as the 2016 Teacher Incentive Fund (TIF) competition, funded projects that encompassed broader HCMS, including spending decisions related to professional development, that supported sustainable performance-based compensation. These competitions focused on projects under which grantees deployed a variety of human capital management strategies throughout an educator's career trajectory (*e.g.,* from pre-service through retention) to help support and sustain the grantees' PBCS. For example, several grantees in these cohorts developed and implemented career ladders to give educators opportunities for leadership and advancement inside and outside the classroom, using program funds to supplement the salaries of master mentor teachers.

Thus, through the two absolute priorities included in this notice, the Department seeks to ensure that this competition supports States and LEAs in their efforts to implement goals and objectives in ESEA consolidated State plans as well as lessons learned from close to two decades of investment and research in HCMS and PBCS.

The Department has established a new definition of High-Need Schools that clarifies the requirement that TSL program activities primarily serve High-Need Schools, and Absolute Priority 2 addresses the extent to which TSL-funded grant project activities are concentrated in High-Need Schools. The Department established the definition and priority based on lessons learned from recent TSL competitions, which highlighted the need to better target the

[1] Throughout this notice, all defined terms are denoted with capitals.

program to educators and students in High-Need Schools.

In addition to Absolute Priority 2, which reinforces the need to serve educators primarily in High-Need Schools, this notice includes two competitive preference priorities aimed at diversifying and strengthening the educator workforce. Competitive Preference Priority 1, Supporting Educators and their Professional Growth, emphasizes the importance of promoting the continued development and growth of educators, including through leadership opportunities. This competitive preference priority focuses on activities that are designed to attract and retain a well-qualified, experienced, effective, and diverse pool of skilled educators. Competitive Preference Priority 2, Increasing Educator Diversity, highlights the critical need to increase the diversity of the educator workforce, to help ensure equity in our education system for the benefit of all students. This competitive preference priority focuses on activities that are designed to address educator diversity through a broader lens of equity and inclusion, with an emphasis on outreach, recruitment, preparation, support, and retention.

Priorities: This notice contains two absolute priorities and two competitive preference priorities. In accordance with 34 CFR 75.105(b)(2)(v), Absolute Priority 1 is from ESEA section 2212(e)(1) and (2); and Absolute Priority 2 is from the TSL notice of final priority and definition published elsewhere in this issue of the **Federal Register** (TSL NFP). In accordance with 34 CFR 75.105(b)(2)(ii), Competitive Preference Priorities 1 and 2 are from the Effective Educator Development (EED) notice of final priorities published elsewhere in this issue of the **Federal Register** (EED NFP).

Absolute Priority: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet both absolute priorities.

These priorities are:

Absolute Priority 1: Human Capital Management Systems (HCMS) or Performance Based Compensation Systems (PBCS).

Under this priority, eligible applicants must propose a project to develop, implement, improve, or expand, in collaboration with teachers, principals, other School Leaders, and members of the public, a PBCS or HCMS.

Applicants that propose to use grant funds, under ESEA section 2212(e)(2)(A), to develop or improve an evaluation and support system as part of an HCMS, in responding to this priority, must describe how such system—

(a) Reflects clear and fair measures of educator performance, based in part on demonstrated improvement in student academic achievement; and

(b) Provides educators with ongoing, differentiated, targeted, and personalized support and feedback for improvement, including professional development opportunities designed to increase effectiveness.

Absolute Priority 2: High-Need Schools.

Under this priority, eligible applicants must concentrate proposed activities on teachers, principals, or other School Leaders serving in High-Need Schools.

In order to demonstrate that the TSL project is concentrated in High-Need Schools, the applicant must—

(a) Provide the requested data in paragraph (c) of this priority to demonstrate that at least the majority of the schools participating in the proposed project are High-Need Schools and describe how the TSL-assisted grant activities are focused on those schools;

(b) Include a list of all schools in which the proposed TSL-funded project would be implemented and indicate which schools are High-Need Schools; and

(c) Provide the most recently available school-level data supporting each school's designation as a High-Need School.

Competitive Preference Priorities: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to 5 points to an application, depending on how well the application meets Competitive Preference Priority 1. We award up to an additional 5 points to an application depending on how well the application meets Competitive Preference Priority 2. An application may be awarded a maximum of 10 additional points under the competitive preference priorities.

These priorities are:

Competitive Preference Priority 1—Supporting Educators and Their Professional Growth. (up to 5 points)

Projects that are designed to increase the number and percentage of well-prepared, experienced, effective, and diverse educators—which may include one or more of the following: Teachers, principals, paraprofessionals, or other School Leaders as defined in section 8101(44) of the ESEA—through Evidence-Based strategies incorporating one or more of the following:

(a) Adopting, implementing, or expanding efforts to recruit, select, prepare, support, and develop talented individuals—to serve as mentors, instructional coaches, principals, or School Leaders in High-Need Schools who have the knowledge and skills to significantly improve instruction.

(b) Implementing practices or strategies that support High-Need Schools in recruiting, preparing, hiring, supporting, developing, and retaining qualified, experienced, effective, and diverse educators.

(c) Increasing the number of teachers with State or national advanced educator certification or certification in a teacher shortage area, as determined by the Secretary, such as special education or bilingual education.

(d) Providing high-quality professional development opportunities to all educators in High-Need Schools on meeting the needs of diverse learners, including students with disabilities and English learners.

Competitive Preference Priority 2—Increasing Educator Diversity. (up to 5 points)

Under this priority, applicants must develop projects that are designed to improve the recruitment, outreach, preparation, support, development, and retention of a diverse educator workforce through adopting, implementing, or expanding one or more of the following:

(a) Educator candidate support and preparation strategies and practices focused on underrepresented teacher candidates, and which may include ''grow your own programs,'' which typically recruit middle or high school students, paraprofessionals, or other school staff and provide them with clear pathways and intensive support to enter the teaching profession.

(b) Professional growth and leadership opportunities for diverse educators, including opportunities to influence school, district, or State policies and practices in order to improve educator diversity.

(c) High-quality professional development on addressing bias in instructional practice and fostering an inclusive, equitable, and supportive workplace and school climate for educators.

(d) Data systems, timelines, and action plans for promoting inclusive and bias-free human resources practices that promote and support development of educator and school leader diversity.

Application Requirements: For FY 2021 and any subsequent year in which we make awards from the list of

unfunded applications from this competition, the following application requirements from ESEA section 2212(c) apply.

Each eligible applicant desiring a grant under this program must submit an application that contains—

(i) A description of the PBCS or HCMS that the eligible entity proposes to develop, implement, improve, or expand through the grant;

(ii) A description of the most significant gaps or insufficiencies in student access to effective educators in High-Need Schools, including gaps or inequities in how effective educators are distributed across the LEA, as identified using factors such as data on school resources, staffing patterns, school environment, educator support systems, and other school-level factors;

(iii) A description and evidence of the support and commitment from educators, which may include charter School Leaders, in the school (including organizations representing educators), the community, and the LEA to the activities proposed under the grant;

(iv) A description of how the eligible entity will develop and implement a fair, rigorous, valid, reliable, and objective process to evaluate educator performance under the system that is based in part on measures of student academic achievement, including the baseline performance against which evaluations of improved performance will be made;

(v) A description of the LEAs or schools to be served under the grant, including student academic achievement, demographic, and socioeconomic information;

(vi) A description of the effectiveness of educators in the LEA and the schools to be served under the grant and the extent to which the system will increase the effectiveness of educators in such schools;

(vii) A description of how the eligible entity will use grant funds under this subpart in each year of the grant, including a timeline for implementation of such activities;

(viii) A description of how the eligible entity will continue the activities assisted under the grant after the grant period ends;

(ix) A description of the State, local, or other public or private funds that will be used to supplement the grant, including funds under Title II, part A of the ESEA, and sustain the activities assisted under the grant after the end of the grant period;

(x) A description of the rationale for the project; how the proposed activities are Evidence-Based; and, if applicable, the prior experience of the eligible entity in developing and implementing such activities; and

(xi) A description of how grant activities will be evaluated, monitored, and publicly reported.

Definitions: The definitions of ''Human Capital Management System'' and ''Performance-Based Compensation System'' are from section 2211 of the ESEA. The definitions of ''Evidence-Based'' and ''School Leader'' are from section 8101 of the ESEA (20 U.S.C. 7801). The definitions of ''Baseline,'' ''Demonstrates a Rationale,'' ''Experimental Study,'' ''Logic Model,'' ''Moderate Evidence,'' ''Project Component,'' ''Promising Evidence,'' ''Quasi-Experimental Design study,'' ''Relevant Outcome,'' ''Strong Evidence,'' and ''What Works Clearinghouse Handbooks (WWC Handbooks)'' are from 34 CFR 77.1. The definition of ''High-Need School'' is from the TSL NFP. These definitions apply to the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Baseline means the starting point from which performance is measured and targets are set.

Demonstrates a Rationale means a key Project Component included in the project's Logic Model is informed by research or evaluation findings that suggest the Project Component is likely to improve Relevant Outcomes.

Evidence-Based, when used with respect to a State, LEA, or school activity, means an activity, strategy, or intervention that—

(1) Demonstrates a statistically significant effect on improving student outcomes or other Relevant Outcomes based on—

(i) Strong Evidence from at least one well-designed and well-implemented Experimental Study;

(ii) Moderate Evidence from at least one well-designed and well-implemented Quasi-Experimental Design Study; or

(iii) Promising Evidence from at least one well-designed and well-implemented correlational study with statistical controls for selection bias; or

(ii)(A) Demonstrates a Rationale based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other Relevant Outcomes; and

(2) Includes ongoing efforts to examine the effects of such activity, strategy, or intervention.

Experimental Study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a Project Component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(1) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the Project Component being evaluated (the treatment group) or not to receive the Project Component (the control group).

(2) A regression discontinuity design study assigns the Project Component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(3) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

High-Need School means a school with 50 percent or more of its enrollment from low-income families as calculated using—

(1) The number of children eligible for a free or reduced-price lunch under the National School Lunch Program (NSLP) (or, if an LEA does not participate in the NSLP, comparable data from another source such as a survey);

(2) If an LEA has one or more schools that participate in the Community Eligibility Provision (CEP) of the NSLP, for any of its schools (*i.e.,* CEP and non-CEP schools), the method in paragraph (1) of this definition or an alternative method approved by the Department; and

(3) For middle and high schools, data from feeder schools that can establish that the middle or high school is a High-Need School under paragraph (1) or (2) of this definition.

Human Capital Management System (HCMS) means a system—

(1) By which an LEA makes and implements human capital decisions, such as decisions on preparation, recruitment, hiring, placement, retention, dismissal, compensation,

professional development, tenure, and promotion; and

(2) That includes a performance-based compensation system.

Logic Model (also referred to as a theory of action) means a framework that identifies key Project Components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the Relevant Outcomes) and describes the theoretical and operational relationships among the key Project Components and Relevant Outcomes.

Moderate Evidence means that there is evidence of effectiveness of a key Project Component in improving a Relevant Outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(1) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(2) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a Relevant Outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a Relevant Outcome; or

(3) A single Experimental Study or Quasi-Experimental Design Study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(i) Meets WWC standards with or without reservations;

(ii) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(iii) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(iv) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same Project Component that each meet requirements in paragraphs (3)(i), (ii), and (iii) of this definition may together satisfy the requirement in this paragraph (3)(iv).

Performance-Based Compensation System (PBCS) means a system of compensation for teachers, principals, or other School Leaders—

(1) That differentiates levels of compensation based in part on measurable increases in student academic achievement; and

(2) Which may include—

(i) Differentiated levels of compensation, which may include bonus pay, on the basis of the employment responsibilities and success of effective teachers, principals, or other School Leaders in hard-to-staff schools or high-need subject areas; and

(ii) Recognition of the skills and knowledge of teachers, principals, or other School Leaders as demonstrated through—

(A) Successful fulfillment of additional responsibilities or job functions, such as teacher leadership roles; and

(B) Evidence of professional achievement and mastery of content knowledge and superior teaching and leadership skills.

Project Component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual Project Component or to a combination of Project Components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising Evidence means that there is evidence of the effectiveness of a key Project Component in improving a Relevant Outcome, based on a relevant finding from one of the following:

(1) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(2) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a Relevant Outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a Relevant Outcome; or

(3) A single study assessed by the Department, as appropriate, that—

(i) Is an Experimental Study, a Quasi-Experimental Design Study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(ii) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a Relevant Outcome.

Quasi-Experimental Design Study means a study using a design that attempts to approximate an Experimental Study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks.

Relevant Outcome means the student outcome(s) or other outcome(s) the key Project Component is designed to improve, consistent with the specific goals of the program.

School Leader means a principal, assistant principal, or other individual who is—

(1) An employee or officer of an elementary school or secondary school, LEA, or other entity operating an elementary school or secondary school; and

(2) Responsible for the daily instructional leadership and managerial operations in the elementary school or secondary school building.

Strong Evidence means that there is evidence of the effectiveness of a key Project Component in improving a Relevant Outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(1) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(2) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' on a Relevant Outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a Relevant Outcome; or

(3) A single Experimental Study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(i) Meets WWC standards without reservations;

(ii) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a Relevant Outcome;

(iii) Includes no overriding statistically significant and negative effects on Relevant Outcomes reported in the study or in a corresponding WWC intervention report prepared under

version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(iv) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same Project Component that each meet requirements in paragraphs (3)(i), (ii), and (iii) of this definition may together satisfy the requirement in this paragraph (3)(iv).

What Works Clearinghouse (WWC) Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbooks documentation.

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 3.0), as well as the more recent What Works Clearinghouse Handbooks released in October 2017 (Version 4.0) and January 2020 (Version 4.1), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

Program Authority: Sections 2211–2213 of the ESEA.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) TSL NFP. (e) EED NFP.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $88,060,000 for new awards.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $500,000 to $8.5 million.

Note: The Department estimates a wide range of awards, given the potentially large differences in the scope of funded projects, including the size and number of participating LEAs.

Estimated Average Size of Awards: $4,000,000.

Estimated Number of Awards: 20–25.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:*

(a) An LEA, including a charter school that is an LEA, or a consortium of LEAs; [2]

(b) A State educational agency (SEA) or other State agency designated by the Chief Executive of a State to participate;

(c) The Bureau of Indian Education; or

(d) A partnership [3] consisting of—

(i) One or more agencies described in paragraph (a), (b), or (c); and

(ii) At least one nonprofit organization as defined in 2 CFR 200.70 or at least one for-profit entity.

Note: An LEA may receive (whether individually or as part of a consortium or partnership) a grant under the TSL program only twice.

Note: The Secretary considers all schools funded by the Department of Interior's Bureau of Indian Education to be LEAs under section 8101(30)(C) of the ESEA.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* Under section 2212(f) of the ESEA, each grant recipient must provide from non-Federal sources an amount equal to 50 percent of the amount of the grant (which may be provided in cash or in kind), to carry out the activities supported by the grant. Applicants and grantees should budget relative to each annual award of TSL grant funds. Applicants are strongly encouraged to take this requirement into account when requesting Federal funds and limit their requests appropriately. Applicants should verify that their budgets reflect both the requested Federal award amount and the matching contribution with appropriate cost allocations. TSL Matching Formula: Total Project Cost multiplied by .67 equals Federal Award Amount.

b. *Supplement-Not-Supplant:* This program involves supplement-not-supplant funding requirements. In accordance with section 2212(g) of the ESEA, funds made available under this program must be used to supplement, and not supplant, other Federal or State funds that would otherwise be expended to carry out activities under this program. The Secretary considers all schools funded by the Department of Interior's Bureau of Indian Education to be LEAs, and the funds that these schools receive from the Department of Interior's annual appropriation to be neither Federal nor State funds. Further, the prohibition against supplanting also means that grantees seeking to charge indirect costs to TSL funds will need to use their negotiated restricted indirect cost rates. See 34 CFR 75.563 for more information.

c. *Indirect Cost Rate Information:* This program uses a restricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

[2] Consistent with ESEA section 2212(b)(3), an LEA may receive a TSL grant (whether individually or as part of an eligible consortium or partnership) only twice.

[3] *See* Id.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c), a grantee under this competition may award subgrants to directly carry out project activities described in its application to the following types of entities: LEAs, SEAs, nonprofit organizations or for-profit organizations. The grantee may award subgrants to entities it has identified in an approved application.

4. *Renewal:* Under section 2212(b)(2) of the ESEA, the Secretary may renew a grant awarded under this section for up to two additional years if the grantee demonstrates to the Secretary that the grantee is effectively using funds. Such renewal may include allowing the grantee to scale up or replicate the successful program.

Note: During the third year of the project period for grants awarded under this competition, if the Department exercises the option to offer an opportunity for renewals, the Department will provide grantees with information on the renewal process. This additional funding is intended not only to support continuation of approved project activities, but also to encourage scaling, replication, and sustainability efforts and strategies. In making decisions on whether to award a two-year renewal award, we intend to review performance data submitted in regularly required reporting, as well as potentially request narrative information to be assessed using selection criteria from 34 CFR 75.210.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for TSL, your application may include business information that you consider proprietary. In 34 CFR 5.11, we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended). Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information. Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program. Please note that, under 34 CFR 79.8(a), we have shortened the standard 60-day intergovernmental review period in order to make awards by the end of FY 2021.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 40 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Calibri, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants who intend to apply. Therefore, we strongly encourage each potential applicant to notify us of the applicant's intent to submit an application. To do so, please email *TSL@ed.gov* with the subject line ''Intent to Apply,'' and include the applicant's name and contact person's name and email address by July 30, 2021. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The following selection criteria for this competition are from 34 CFR 75.210. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following its title.

(a) *Need for project* (25 points)

(1) The Secretary considers the need for the proposed project.

(2) In determining evidence of the need for the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(ii) The extent to which the proposed project will integrate with or build on similar or related efforts to improve Relevant Outcomes using existing funding streams from other programs or policies supported by community, State, and Federal resources.

(iii) The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

(iv) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(b) *Quality of the project design* (30 points)

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project Demonstrates a Rationale.

(ii) The extent to which the design of the proposed project includes a thorough, high-quality review of the relevant literature, a high-quality plan for project implementation, and the use of appropriate methodological tools to ensure successful achievement of project objectives.

(iii) The extent to which the methods of evaluation will provide performance

feedback and permit periodic assessment of progress toward achieving intended outcomes.

(c) *Quality of the management plan* (20 points)

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(d) *Adequacy of resources* (25 points)

(1) The Secretary considers the adequacy of resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The likelihood that the proposed project will result in system change or improvement.

(ii) The extent to which the proposed project is likely to build local capacity to provide, improve, or expand services that address the needs of the target population.

(iii) The extent to which the applicant demonstrates that it has the resources to operate the project beyond the length of the grant, including a multi-year financial and operating model and accompanying plan; the demonstrated commitment of any partners; evidence of broad support from stakeholders (*e.g.,* SEAs, teachers' unions) critical to the project's long-term success; or more than one of these types of evidence.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions, and under 2 CFR 3474.10 in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115—232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the

necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

Note: In addition, under 34 CFR 75.591, all TSL grantees must cooperate in any evaluation of the program conducted by the Department.

5. *Performance Measures:* The goal of TSL is to support educators, particularly those in High-Need Schools, to raise student academic achievement and close the achievement gap between high- and low-performing students. We have established performance measures for this program: (a) The percentage of teachers and School Leaders within the TSL-assisted schools rated effective or higher by their districts' evaluation and support systems; (b) the percentage of teachers and School Leaders across the participating district(s) that show improvements, over the previous year, on the student growth component of their evaluation rating; (c) the percentage of teachers and School Leaders within the TSL-assisted schools that show improvements, over the previous year, on the student growth component of their evaluation rating; (d) the percentage of teachers and School Leaders in TSL-assisted schools for whom evaluation ratings were used to inform decisions regarding recruitment, hiring, placement, retention, dismissal, professional development, tenure, promotion, or all of the above; (e) the percentage of teachers and School Leaders within the participating district(s) who earned performance-based compensation based on their individual evaluation ratings; (f) the percentage of teachers and School Leaders in TSL-funded schools who earned performance-based compensation based on their individual evaluation ratings; (g) the number of teachers receiving performance compensation disaggregated by race, gender, and where available, disability status; (h) the number of School Leaders receiving performance compensation disaggregated by race, gender, and where available, disability status; and (i) the number of teachers receiving performance compensation for leadership responsibilities disaggregated by race, gender, and where available, disability status.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package 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.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021–14714 Filed 7–8–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[EERE–2021–BT–BC–0013]

Future of Energy Codes Workshop; Reopening of the Public Comment Period

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

ACTION: Reopening of the public comment period.

SUMMARY: The U.S. Department of Energy (DOE) is reopening the public comment period for the request for public comments on its public stakeholder workshop on the Future of Energy Codes held June 22 and 24, 2021. DOE published notice of the workshop on June 14, 2021 and requested comments by July 8, 2021. On June 30, 2021, DOE received a request from the American Gas Association, American Public Gas Association, National Association of Home Builders, and National Propane Gas Association to extend the public comment period by 45 days. DOE is reopening the public comment period until July 31, 2021.

DATES: The comment period associated with the Future of Energy Codes Workshop, held on June 22 and 24, 2021 (86 FR 31491) is reopened. DOE will accept stakeholder comments and feedback from the Workshop on or before July 31, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2021–BT–BC–0013 by any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email:* To *buildingenergycodes workshop2021BC0013@ee.doe.gov.* Include docket number EERE–2021–BT–

BC–0013 in the subject line of the message.

No telefacsimilies (''faxes'') will be accepted.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing COVID–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact the parties listed below to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure. The docket web page can be found at: *www.regulations.gov/docket/EERE-2021-BT-BC-0013.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Jeremiah Williams; U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, EE–5B, Washington, DC 20585; (202) 287–1941; *Jeremiah.Williams@ee.doe.gov*.

For legal issues, please contact Matthew Ring; U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW, GC–33, Washington, DC 20585; (202) 586–2555; *Matthew.Ring@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: On June 14, 2021, DOE published notice of a stakeholder workshop on the Future of Energy Codes (86 FR 31491), which was subsequently held on June 22 and 24, 2021. The workshop highlighted leading advancements in energy codes, bringing together key stakeholders from across the design and construction industry to discuss recent code updates, upcoming trends, as well as opportunities and challenges facing code implementation. In parallel with the workshop, a public docket was made available to provide interested stakeholders the option of submitting written comments, in addition to participating directly in the workshop, with comments requested by July 8, 2021. (86 FR 31491) On June 30, 2021, DOE received a request from the American Gas Association, American Public Gas Association, National Association of Home Builders, and National Propane Gas Association to extend the public comment period by 45 days. These interested parties asked for additional time to review the workshop materials, consider the questions presented, and in recognition that the original comment period included a federal holiday.

After considering the request, DOE finds that a 45-day extension of the initial comment period would unnecessarily delay DOE's ability to utilize information provided in the workshop and in comments. Such delay would also hinder its ability to effectively participate in and support the processes for updating building energy codes. However, DOE recognizes the concerns presented in the request, and DOE believes that a brief reopening of the comment period will enable the public to better review and comment on the information presented at the workshop. Accordingly, DOE finds it appropriate to reopen the comment period and will accept comments until July 31, 2021. DOE will consider any comments received by this date to be timely submitted.

Signing Authority

This document of the Department of Energy was signed on July 2, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 2, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–14576 Filed 7–8–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1061–103]

Pacific Gas and Electric Company; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Major, new license.

b. *Project No.:* P–1061–103.

c. *Date filed:* August 24, 2020.

d. *Applicant:* Pacific Gas and Electric Company.

e. *Name of Project:* Phoenix Hydroelectric Project.

f. *Location:* The existing project is located on the South Fork Stanislaus River and in the Tuolumne River Basin, in Tuolumne County, California. The project occupies 26.99 acres of federal land administered by the U.S. Forest Service and 0.59 acres administered by the Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Jan Nimick, Vice President, Power Generation, Pacific Gas and Electric Company, 245 Market Street, San Francisco, CA 94105, (415) 973–0629.

i. *FERC Contact:* Jim Hastreiter, (503) 552–2760 or *james.hastreiter@ferc.gov.*

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room

1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–1061–103.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is ready for environmental analysis at this time.

l. The existing Phoenix Hydroelectric Project operates to provide water to the Tuolumne Utility District, generate power, and meet streamflow requirements for the South Fork Stanislaus River. The project consists of the following existing facilities: (1) A 535-foot-long and 132-foot-high concrete arch dam on the South Fork Stanislaus River, (2) a 172.3 acre reservoir, (3) a 133.1-foot-long and 20-foot-high concrete arch cushion dam, (4) a 15.38-mile-long Main Tuolumne Canal, (5) a Header Box (forebay), a 5,611-foot-long penstock, and a powerhouse with an impulse turbine rated at 1.6 megawatts. The project is estimated to generate an average of 9,956 megawatt-hours annually.

PG&E does not propose any new developments at this time. However, PG&E proposes to modify the existing project boundary to encompass all facilities necessary for operation and maintenance of the project. PG&E proposes to include 21 roads and 14 trails within the project boundary and adjust the boundary around Lyons Reservoir, along the MTC and several of its spill channels, and along the penstock. The area of federal land within the project boundary will increase for Bureau of Land Management lands to 1.55 acres and National Forest Lands to 29.78 acres. With the proposed boundary changes, the overall lands within the project boundary will increase to 348.5 acres

m. 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 website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document (*i.e.,* P–1061). At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support.

All filings must (1) bear in all capital letters the title ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification. Please note that the certification request must comply with 40 CFR 121.5(b), including documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request. Please also note that the certification request must be sent to the certifying authority and to the Commission concurrently.

o. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Deadline for Filing Comments, Recommendations, and Agency Terms and Conditions/Prescriptions—August 31, 2021
Licensee's Reply to REA Comments—October 15, 2021
Commission issues Draft EA—May 2022
Comments on EA—June 2022
Commission issues Final EA—September 2022
Commission issues license order—December 2022

Dated: July 2, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–14624 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–88–000]

Great River Energy; Notice of Filing

Take notice that on July 1, 2021, Great River Energy (GRE), filed a revised revenue requirement for providing Reactive Supply and Voltage Control from Generation or Other Sources Service (Reactive Power Service) supplied by GRE's generation resources located in the Midcontinent Independent System Operator, Inc.'s region.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention 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 Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on July 22, 2021.

Dated: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14669 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2336–000]

Tecolote Wind 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 Tecolote Wind 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 July 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: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14665 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2333–000]

Red Cloud Wind, 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 Red Cloud Wind 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 July 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: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14666 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–87–000]

Arkansas River Power Authority, Delta-Montrose Electric Association, and Kit Carson Electric Cooperative, Inc. v. Tri-State Generation and Transmission Association, Inc.; Notice of Complaint

Take notice that on June 28, 2021, pursuant to sections 206, 306, and 309 of the Federal Power Act, 16 U.S.C. 824e, 825e, 825h and Rules 206 and 212 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and 385.212 (2020), Arkansas River Power Authority (ARPA), Delta-Montrose Electric Association, and Kit Carson Electric Cooperative, Inc. (Joint Complaints) filed a formal complaint against Tri-State Generation and Transmission Association, Inc. (Tri-State or Respondent), alleging that Respondent's Open Access Transmission Tariff rates are unjust, unreasonable, unduly discriminatory, and preferential, all as more fully explained in the complaint.

The Joint Complainants certifies that copies of the complaint were served on representatives for Tri-State, and on all parties to Docket Nos. ER20–686–000 and ER20–2009–001 (consolidated), and EL20–25–000, ER20–688–000, ER20–726–000, and ER20–728–000 (not consolidated). Additionally, ARPA certifies that a non-public copy of the Complaint was served on representatives for Tri-State.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://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.

Comment Date: 5:00 p.m. Eastern Time on July 28, 2021.

Dated: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14662 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–466–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on June 22, 2021, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 700, Houston, Texas 77002–2700, filed in the above referenced docket a prior notice pursuant to Section 157.205 and 157.216 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act and the blanket certificate issued to Columbia by the Commission in Docket No. CP83–76–000,[1] seeking for authorization to abandon four injection/withdrawal wells, their associated pipelines and appurtenances, located in its Donegal and Dundee Storage Fields in Washington County, Pennsylvania and Schuyler County, New York. These abandonments will include the abandonment in-place and by-removal of associated pipelines shown in detail on a table in the application. Columbia states that the abandonment will: (1) Reduce public risk of unintended gas release from deteriorating wellheads and pipelines; (2) reduce the risk of customer gas being lost from reservoirs due to deteriorating subsurface conditions; and (3) eliminate the need for future expenditures associated with these assets. Further, Columbia avers that the proposed abandonments will not affect any firm service to any existing customers, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://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.

Any questions concerning this application should be directed to Sorana Linder, Director, Modernization & Certificates, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, by telephone (832) 320–5209, or by email at *sorana_linder@tcenergy.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you

[1] *Columbia Gas Transmission Corporation* (predecessor to Columbia Gas Transmission, LLC), 22 FERC ¶ 62,029 (1983).

can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on August 31, 2021. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is August 31, 2021. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is August 31, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before August 31, 2021. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP21–466–000 in your submission. The Commission encourages electronic filing of submissions.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission. Your submission must reference the Project docket number CP21–466–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: *sorana_linder@tcenergy.com* or 700 Louisiana Street, Suite 700, Houston, Texas 77002–2700. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: July 2, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–14627 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–57–000]

Mountain Valley Pipeline, LLC; Notice of Supplemental Scoping Period for the Proposed Amendment to the Certificate of Public Convenience and Necessity for the Mountain Valley Pipeline Project and Request for Comments on Environmental Issues

On March 16, 2021, Commission staff issued a ''Notice of Scoping Period and Requesting Comments on Environmental Issues for the Proposed Amendment to the Certificate of Public Convenience and Necessity for the Mountain Valley Pipeline Project'' (Notice of Scoping). The Notice of Scoping is included as attachment 1.[1] The scoping comment period ended on April 15, 2021.

It has come to our attention that the entire environmental mailing list may not have received copies of the Notice of Scoping; therefore, the Commission is issuing this Notice of Supplemental Scoping Period to provide interested parties that did not receive the previous notice an opportunity to file comments on environmental issues. The supplemental scoping period will close on August 2, 2021.

The staff of the Commission is preparing an environmental assessment (EA) that will discuss the environmental impacts of the proposed Amendment to the Certificate of Public Convenience and Necessity for the Mountain Valley Pipeline Project (Amendment Project) involving construction and operation of facilities by Mountain Valley Pipeline, LLC (Mountain Valley) in Wetzel, Lewis, Webster, Nicholas, Greenbrier, Summers, and Monroe Counties, West Virginia and Giles, Montgomery, Roanoke, Franklin, and Pittsylvania Counties, Virginia.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Commission staff will consider all written comments during the preparation of the EA. If you submitted comments in Docket No. CP21–57–000 during the previous scoping period, those comments will be considered and do not need to be resubmitted.

On June 11, 2021, Commission staff issued a ''Notice of Schedule for the Preparation of an Environmental Assessment for the Proposed Amendment to the Certificate of Public Convenience and Necessity for the Mountain Valley Pipeline Project'' (Notice of Schedule).[2] As indicated in the Notice of Schedule, the EA is scheduled to be published on August 13, 2021. If a schedule change becomes necessary, the Commission will issue a revised schedule.

Additional information on the Amendment Project including how to submit comments to the Commission, a summary of the proposed project, the NEPA Process, and information on the environmental mailing list can be found in the Notice of Scoping included in attachment 1.

Additional information about the project is also available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Dated: July 1, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–14626 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary''. For instructions on connecting to eLibrary, refer to the last page of this notice. At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[2] See accession number 20210611–3044.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2322–069]

Brookfield White Pine Hydro LLC; Notice of Availability of Draft Environmental Assessment and Revised Procedural Schedule

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Shawmut Hydroelectric Project, located on the Kennebec River in Kennebec and Somerset Counties, Maine, and has prepared a Draft Environmental Assessment (DEA) for the project. No federal land is occupied by project works or located within the project boundary.

The DEA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (*http://www.ferc.gov/*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters,

without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2322–069.

With this notice, we are waiving section 5.25(a) of the Commission's regulations that require the DEA to be issued no later than 180 days from the date responses are due to the notice of acceptance and ready for environmental analysis. Instead, the license application will be processed according to the following revised procedural schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Issue Draft EA	July 2021.
Comments on Draft EA due.	August 2021.
Modified terms and conditions due.	October 2021.
Commission issues Final EA.	January 2022.

For further information, contact Matt Cutlip at (503) 552–2762, or by email at *matt.cutlip@ferc.gov.*

Dated: July 1, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–14629 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2331–000]

Duran Mesa 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 Duran Mesa 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 July 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: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14667 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2136–017.

Applicants: Invenergy Cannon Falls LLC.

Description: Triennial Market Power Analysis for Central Region of Invenergy Cannon Falls LLC.

Filed Date: 6/30/21.

Accession Number: 20210630–5347.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER10–2417–004; ER13–122–004.

Applicants: ExxonMobil Baton Rouge Complex, ExxonMobil Beaumont Complex.

Description: Triennial Market Power Analysis for Central Region of ExxonMobil Baton Rouge Complex, et al.

Filed Date: 6/30/21.

Accession Number: 20210630–5352.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER10–2421–007; ER10–2616–021; ER10–3247–014; ER11–2457–007; ER11–4398–009; ER11–4400–017; ER12–2250–008; ER12–2251–008; ER12–2252–009; ER12–2253–008; ER14–1569–014; ER14–2245–008; ER14–883–015; ER14–922–007; ER14–924–007; ER15–1161–001; ER15–1596–014; ER15–1599–014; ER15–2535–004; ER19–102–007; ER19–158–009; ER19–2608–001; ER19–2803–006; ER19–2806–006; ER19–2807–006; ER19–2809–006; ER19–2810–006; ER19–2811–006.

Applicants: Energy Services Providers, Inc., Ambit Northeast, LLC, Cincinnati Bell Energy LLC, Connecticut Gas & Electric, Inc., Dynegy Energy Services, LLC, Dynegy Energy Services (East), LLC, Dynegy Marketing and Trade, LLC, Dynegy Midwest Generation, LLC, Dynegy Power Marketing, LLC, Electric Energy, Inc., Energy Rewards, LLC, Everyday Energy NJ, LLC, Everyday Energy, LLC, Illinois Power Generating Company, Illinois Power Marketing Company, Illinois Power Resources Generating, LLC, Luminant Commercial Asset Management LLC, Luminant Energy Company LLC, Massachusetts Gas &

Electric, Inc., Midwest Electric Power, Inc., Public Power & Utility of Maryland, LLC, Public Power & Utility of NY, Inc, Public Power, LLC, Public Power, LLC (PA), TriEagle Energy, LP, Viridian Energy, LLC, Viridian Energy NY, LLC, Viridian Energy PA, LLC.

Description: Triennial Market Power Analysis for Central Region of Energy Services Providers, Inc, et al.

Filed Date: 6/29/21.

Accession Number: 20210629–5274.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER11–2105–005.

Applicants: Oklahoma Gas and Electric Company.

Description: Triennial Market Power Analysis for Southwest Power Pool, Inc. Region of Oklahoma Gas and Electric Company.

Filed Date: 6/30/21.

Accession Number: 20210630–5354.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER11–4044–026.

Applicants: Gratiot County Wind LLC.

Description: Triennial Market Power Analysis for Central Region of Gratiot County Wind LLC.

Filed Date: 6/30/21.

Accession Number: 20210630–5348.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER11–4046–025.

Applicants: Gratiot County Wind II LLC.

Description: Triennial Market Power Analysis for Central Region of Gratiot County Wind II LLC.

Filed Date: 6/30/21.

Accession Number: 20210630–5349.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER11–4267–017; ER11–113–013; ER11–4694–009; ER12–1680–010; ER17–2084–003; ER20–967–001; ER21–44–003.

Applicants: Algonquin Energy Services Inc., Altavista Solar, LLC, GSG 6, LLC, Sandy Ridge Wind, LLC, Minonk Wind, LLC, Great Bay Solar I, LLC, Great Bay Solar II, LLC.

Description: Notice of Non-Material Change in Status of Algonquin Energy Services Inc., et al.

Filed Date: 6/30/21.

Accession Number: 20210630–5355.

Comments Due: 5 p.m. ET 7/21/21.

Docket Numbers: ER16–1720–018.

Applicants: Invenergy Energy Management LLC.

Description: Triennial Market Power Analysis for Central Region of Invenergy Energy Management LLC.

Filed Date: 6/30/21.

Accession Number: 20210630–5350.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER16–2320–009.

Applicants: Pacific Gas and Electric Company.

Description: Compliance filing: TO18 Tax Act Compliance Filing to be effective N/A.

Filed Date: 7/2/21.

Accession Number: 20210702–5061.

Comments Due: 5 p.m. ET 7/23/21.

Docket Numbers: ER16–2703–005; ER10–2738–011; ER11–4267–016; ER15–2631–008; ER20–2379–003.

Applicants: Deerfield Wind Energy, LLC, Odell Wind Farm, LLC, The Empire District Electric Company, Algonquin Energy Services Inc., Sugar Creek Wind One LLC.

Description: Triennial Market Power Analysis for Central Region of Deerfield Wind Energy, LLC, et al.

Filed Date: 6/30/21.

Accession Number: 20210630–5351.

Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER20–2004–001.

Applicants: Public Service Electric and Gas Company, PJM Interconnection, L.L.C.

Description: Compliance filing: PSEG submits Order 864 Compliance Filing re: Deficiency Letter to be effective N/A.

Filed Date: 7/2/21.

Accession Number: 20210702–5008.

Comments Due: 5 p.m. ET 7/23/21.

Docket Numbers: ER21–1660–000.

Applicants: Arizona Public Service Company.

Description: Report Filing: Service Agreement No. 363—Refund Report to be effective N/A.

Filed Date: 7/2/21.

Accession Number: 20210702–5058.

Comments Due: 5 p.m. ET 7/23/21.

Docket Numbers: ER21–2343–000.

Applicants: Guzman Energy LLC.

Description: Petition for Limited Waiver of Guzman Energy LLC.

Filed Date: 7/1/21.

Accession Number: 20210701–5316.

Comments Due: 5 p.m. ET 7/16/21.

Docket Numbers: ER21–2346–000.

Applicants: Bellingham Power Generation LLC.

Description: Compliance filing: Notices of Succession and Revisions to Tariffs Refiling under ER21–1894 to be effective 4/16/2021.

Filed Date: 7/2/21.

Accession Number: 20210702–5032.

Comments Due: 5 p.m. ET 7/23/21.

Docket Numbers: ER21–2347–000.

Applicants: Blackstone Power Generation LLC.

Description: Compliance filing: Notices of Succession and Revisions to Tariffs Refiling under ER21–1895 to be effective 4/16/2021.

Filed Date: 7/2/21.

Accession Number: 20210702–5035.

Comments Due: 5 p.m. ET 7/23/21.

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: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14664 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–493–000]

Tennessee Gas Pipeline Company, L.L.C.; Notice of Availability of the Draft Environmental Impact Statement for the Proposed East 300 Upgrade Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft environmental impact statement (EIS) for the East 300 Upgrade Project, proposed by Tennessee Gas Pipeline Company, L.L.C. (Tennessee) in the above-referenced docket. Tennessee requests authorization to modify two existing compressor stations and construct one new compressor station in Pennsylvania and New Jersey to create 115 million cubic feet per day of firm transportation capacity on Tennessee's existing 300 Line for Consolidated Edison Company of New York, Inc.

The draft EIS responds to comments that were received on the Commission's February 19, 2021 environmental assessment (EA) [1] and discloses downstream greenhouse gas emissions for the project. With the exception of climate change impacts, the FERC staff concludes that approval of the proposed

[1] The project's EA is available on eLibrary under accession no. 20210219–3034.

project, with the mitigation measures recommended in this EIS, would not result in significant environmental impacts. FERC staff continues to be unable to determine significance with regards to climate change impacts.

The draft EIS incorporates the above-referenced EA, which addressed the potential environmental effects of the construction and operation of the following project facilities:

- Modifications at existing Compressor Station 321 in Susquehanna County, Pennsylvania, including the installation of one Solar Taurus 70 turbine with an International Organization for Standardization (ISO) rating of 11,107 horsepower and auxiliary facilities;
- modifications at existing Compressor Station 325 in Sussex County, New Jersey, including installation of one Solar Titan 130 turbine with an ISO rating of 20,500 horsepower and auxiliary facilities; and
- construction of the new Compressor Station 327 equipped with a single 19,000-horsepower electric-driven compressor unit and associated auxiliary facilities in Passaic County, New Jersey.

The Commission mailed a copy of the *Notice of Availability of the Draft Environmental Impact Statement for the Proposed East 300 Upgrade Project* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the project area. The draft EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the draft EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*), select ''General Search,'' and enter the docket number in the ''Docket Number'' field (*i.e.,* CP20–493). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

The draft EIS is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding. Any person wishing to comment on the draft EIS may do so. Your comments should focus on the draft EIS's disclosure and discussion of potential environmental effects, including climate impacts due to downstream greenhouse gas emissions, and measures to avoid or lessen environmental impacts. To ensure consideration of your comments on the proposal in the final EIS, it is important that the Commission receive your comments on or before 5:00 p.m. Eastern Time on August 23, 2021.

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP20–493–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR part 385.214). Motions to intervene are more fully described at *https://www.ferc.gov/ferc-online/ferc-online/how-guides.* Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Questions?

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings. In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: July 2, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–14625 Filed 7–8–21; 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 exempt wholesale generator filings:

Docket Numbers: EG21–192–000.
Applicants: Jayhawk Wind, LLC.
Description: Notice of Self-Certification of Jayhawk Wind, LLC.
Filed Date: 6/28/21.
Accession Number: 20210628–5189.
Comments Due: 5 p.m. ET 7/19/21.

Docket Numbers: EG21–193–000.
Applicants: Minonk Stewardship Wind LLC.
Description: Notice of Self-Certification as Exempt Wholesale Generator of Minonk Stewardship Wind LLC.
Filed Date: 7/1/21.
Accession Number: 20210701–5287.
Comments Due: 5 p.m. ET 7/22/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1790–019; ER10–2596–011; ER11–3325–006; ER21–1716–001.
Applicants: BP Energy Company, BP Energy Retail LLC, Fowler Ridge II Wind Farm LLC, Whiting Clean Energy, Inc.
Description: Triennial Market Power Analysis for Central Region of BP Energy Company, et al.
Filed Date: 6/29/21.
Accession Number: 20210629–5273.
Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER10–1817–024.
Applicants: Southwestern Public Service Company.
Description: Triennial Market Power Analysis for Southwest Power Pool, Inc. Region of Southwestern Public Service Company.
Filed Date: 6/30/21.
Accession Number: 20210630–5335.
Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER10–1936–009.
Applicants: Carville Energy LLC.
Description: Triennial Market Power Analysis for Central Region of Carville Energy LLC.
Filed Date: 6/30/21.
Accession Number: 20210630–5331.
Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER10–2738–010; ER11–4267–015; ER20–2586–003; ER20–2587–002.
Applicants: The Empire District Electric Company, Algonquin Energy Services Inc., North Fork Ridge Wind, LLC, Kings Point Wind, LLC, Neosho Ridge Wind, LLC.
Description: Triennial Market Power Analysis for Southwest Power Pool, Inc. Region of The Empire District Electric Company, et al.
Filed Date: 6/30/21.
Accession Number: 20210630–5345.
Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER12–1933–013; ER12–1934–011.
Applicants: Interstate Power and Light Company, Wisconsin Power and Light Company.
Description: Triennial Market Power Analysis for Central Region of Interstate Power and Light Company, et al.
Filed Date: 6/30/21.
Accession Number: 20210630–5344.
Comments Due: 5 p.m. ET 8/30/21.

Docket Numbers: ER20–2004–001.
Applicants: Public Service Electric and Gas Company, PJM Interconnection, L.L.C.
Description: Compliance filing: PSEG submits Order 864 Compliance Filing re: Deficiency Letter to be effective N/A.
Filed Date: 7/2/21.
Accession Number: 20210702–5008.
Comments Due: 5 p.m. ET 7/23/21.

Docket Numbers: ER20–2408–002.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2021–06–29 SA 3524 Ameren-Broadlands Wind Farm Sub FSA for FCA (J468) to be effective 10/1/2020.
Filed Date: 6/29/21.
Accession Number: 20210629–5126.
Comments Due: 5 p.m. ET 7/20/21.

Docket Numbers: ER21–1018–002.
Applicants: New York Independent System Operator, Inc.
Description: Compliance filing: NYISO Compliance, Notice of Effective Date, Operating Reserve Demand Curves to be effective 7/13/2021.
Filed Date: 6/29/21.
Accession Number: 20210629–5200.
Comments Due: 5 p.m. ET 7/20/21.

Docket Numbers: ER21–2084–000.
Applicants: Coso Geothermal Power Holdings, LLC.
Description: Amendment to June 4, 2021 Coso Geothermal Power Holdings, LLC tariff filing.
Filed Date: 6/30/21.
Accession Number: 20210630–5224.
Comments Due: 5 p.m. ET 7/21/21.

Docket Numbers: ER21–2334–000.
Applicants: Cross-Sound Cable Company, LLC.
Description: § 205(d) Rate Filing: Schedule 17 Reg Asset Filing to be effective 9/1/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5173.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2335–000.
Applicants: NorthWestern Corporation.
Description: § 205(d) Rate Filing: SA 925—Firm PTP Transmission Service Agreement with Energy Keepers Inc. to be effective 9/1/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5176.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2336–000.
Applicants: Tecolote Wind LLC.
Description: Baseline eTariff Filing: Tecolote Wind LLC MBR Tariff and Joint Application to be effective 7/1/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5177.
Comments Due: 5 p.m. ET 7/22/21,

Docket Numbers: ER21–2337–000.
Applicants: ISO New England Inc., Eversource Energy Service Company.
Description: § 205(d) Rate Filing: PTO AC; Modifications to Monthly Regional Network Load Calculation to be effective 9/1/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5189.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2338–000.
Applicants: PacifiCorp.
Description: Tariff Cancellation: Termination of WAPA Transmission Capacity Sharing in TOT 4A/4B to be effective 9/2/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5226.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2339–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: WAPA Transmission Capacity Sharing in AW/TOT 4B (RS 758) to be effective 9/2/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5227.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2340–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: § 205(d) Rate Filing: Amendment BULK Storage-TRACE to be effective 7/1/2021.
Filed Date: 7/1/21.
Accession Number: 20210701–5236.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2341–000.
Applicants: Appalachian Power Company.
Description: § 205(d) Rate Filing: OATT—Revise Attachment K, AEP Texas Inc. Rate Update to be effective 12/31/9998.
Filed Date: 7/1/21.
Accession Number: 20210701–5256.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2342–000.
Applicants: ISO New England Inc.
Description: ISO New England Inc., Filing of Permanent De-List Bids, Retirement De-List Bids and Substitution Auction Test Prices Submitted for Forward Capacity Auction (FCA 16).
Filed Date: 7/1/21.
Accession Number: 20210701–5310.
Comments Due: 5 p.m. ET 7/22/21.

Docket Numbers: ER21–2344–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA, SA No. 6092; Queue No. AD1–061/AF2–184 to be effective 6/2/2021.
Filed Date: 7/2/21.
Accession Number: 20210702–5009.
Comments Due: 5 p.m. ET 7/23/21.

Docket Numbers: ER21–2345–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA, SA No. 5825; Queue No. AF2–401 re: withdrawal to be effective 7/10/2021.

Filed Date: 7/2/21.
Accession Number: 20210702–5010.
Comments Due: 5 p.m. ET 7/23/21.

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: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14663 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2330–000]

Clines Corners Wind Farm 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 Cline Corners Wind Farm 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 July 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: July 2, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–14668 Filed 7–8–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9057–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed June 28, 2021 10 a.m. EST
Through July 2, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210087, Draft, USFS, OR, Youngs Rock Rigdon, Comment Period Ends: 08/23/2021, Contact: Hilary Krieger 541–460–0754.

EIS No. 20210088, Final, USFS, CO, Berlaimont Estates Access Route, Review Period Ends: 08/09/2021, Contact: Leanne Veldhuis 970–471–1796.

EIS No. 20210089, Final, FRA, GA, Atlanta to Charlotte Rail Corridor Investment Plan, Contact: John Winkle 202–493–6067.

Under 23 U.S.C. 139(n)(2), FRA has issued a single document that consists of a final environmental impact statement and record of decision. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

EIS No. 20210090, Draft, NOAA, NY, Proposed Lake Ontario National Marine Sanctuary Draft Environmental Impact Statement and Draft Management Plan, Comment Period Ends: 09/10/2021, Contact: Ellen Brody 734–276–6387.

EIS No. 20210091, Third Final Supplemental, USFS, AK, Kensington Gold Mine Plan of Operations Amendment 1, Review Period Ends: 08/23/2021, Contact: Matthew Reece 907–789–6274.

EIS No. 20210092, Draft, USAF, ID, Airspace Optimization for Readiness for Mountain Home Air Force Base, Comment Period Ends: 08/23/2021, Contact: Robin Divine 210–925–2730.

EIS No. 20210093, Final Supplement, USFS, ID, Clear Creek Integrated Restoration Project, Review Period Ends: 08/09/2021, Contact: Karen Ritland 208–963–4203.

EIS No. 20210094, Draft, FERC, PA, East 300 Upgrade Project, Comment Period Ends: 08/23/2021, Contact: Office of External Affairs 866–208–3372.

Dated: July 2, 2021.

Candi Schaedle,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–14618 Filed 7–8–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 9, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *HBT Financial Inc., Bloomington, Illinois;* to acquire NXT Bancorporation, Inc., Central City, Iowa, and thereby indirectly acquire NXT Bank, also of Central City, Iowa.

B. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *GrahamJB6 Company, Kingwood, Texas;* to become a bank holding company by acquiring Security Bancshares, Inc., Waco, Texas, and thereby indirectly acquiring voting shares of Citizens State Bank, Woodville, Texas.

C. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *RCB Holding, Inc., Claremore, Oklahoma;* to merge with Oklahoma State Bancshares, Inc., Vinita, Oklahoma, and thereby indirectly acquire Oklahoma State Bank, also of Vinita, Oklahoma, and Lakeside State Bank, Oologah, Oklahoma.

2. *Sooner Southwest Bankshares, Inc., Tulsa, Oklahoma;* to merge with Capital Bank Holdings, Inc., and thereby indirectly acquire Oklahoma Capital Bank, both of Tulsa, Oklahoma.

Board of Governors of the Federal Reserve System, July 6, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–14657 Filed 7–8–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10215, CMS–10249, and CMS–10341]

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 *August 9, 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 currently approved collection; *Title of Information Collection:* Identifying Medicaid Payment for Physician Administered Drugs; *Use:* States are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for ''J'' code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars. *Form Number:* CMS–10215 (OMB control number: 0938–1026); *Frequency:* Weekly; *Affected Public:* Business or other for-profits and Not-

for-profit institutions); *Number of Respondents:* 20,000; *Total Annual Responses:* 4,589,433; *Total Annual Hours:* 351,046. (For policy questions regarding this collection contact Michael Forman at 410–786–2666.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Administrative Requirements for Section 6071 of the Deficit Reduction Act; *Use:* State Operational Protocols should provide enough information such that: the CMS Project Officer and other federal officials may use it to understand the operation of the demonstration, prepare for potential site visits without needing additional information, or both; the State Project Director can use it as the manual for program implementation; and external stakeholders may use it to understand the operation of the demonstration. The financial information collection is used in our financial statements and shared with the auditors who validate CMS' financial position. The Money Follows the Person Rebalancing Demonstration (MFP) Finders File, MFP Program Participation Data file, and MFP Services File are used by the national evaluation contractor to assess program outcomes while we use the information to monitor program implementation. The MFP Quality of Life data is used by the national evaluation contractor to assess program outcomes. The evaluation is used to determine how participants' quality of life changes after transitioning to the community. The semi-annual progress report is used by the national evaluation contractor and CMS to monitor program implementation at the grantee level. The revisions aim to reduce the reporting burden by presenting a substantially revised and shorted version of the semi-annual progress report. The budget workbook has also been revised to combine two earlier reporting forms. *Form Number:* CMS–10249 (OMB control number: 0938–1053); *Frequency:* Yearly, quarterly, and semi-annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 42; *Total Annual Responses:* 336; *Total Annual Hours:* 2,604. (For policy questions regarding this collection contact Todd Wilson at 410–786–3409.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; *Use:* This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. *Form Number:* CMS–10341 (OMB control number: 0938–1162); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 37; *Total Annual Responses:* 372; *Total Annual Hours:* 27,914. (For policy questions regarding this collection contact Tonya Moore at 410–786–0019.)

Dated: July 6, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–14671 Filed 7–8–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2347]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificates

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 9, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0793. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Cosmetic Export Certificates

OMB Control Number 0910–0793—Extension

Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a ''certificate.'' In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for human food and cosmetic products. Interested persons may request a certificate electronically via the CFSAN Export Certification Application and Tracking System (CFSAN eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting CFSAN for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. For food products, respondents are able to identify facilities using their Food Facility Registration, an FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter

product information, particularly for applications that include multiple products.

All information is entered using electronic Forms FDA 3613d, 3613e, and 3613k and used to evaluate certificate requests. The eCATS Module is Form FDA 3613k, where Form FDA 3613e is the Certificate of Free Sale (*https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food*). All ''forms'' are electronic and part of the eCATS or CAP portal accessed via *https://www.access.fda.gov.* To view representations of the forms, you have to download the instructions, which are accessible from the following links: *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

While burden associated with information collection activities for export certificates issued for other FDA-regulated products is approved under OMB control number 0910–0498, this collection specifically supports export certificates issued by CFSAN. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact CFSAN directly by email (*CFSANExportCertification@fda.hhs.gov*) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and instructions for requesting export certificates for food (Forms FDA 3613e and 3613k) are available online at *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

In the **Federal Register** of March 16, 2021 (86 FR 14452), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment offering general support for our cosmetic export certificate program. The comment also recommended FDA consider providing certificates that allow exporters to use an exemption from requirements in China for animal testing for certain imported cosmetic products. We appreciate the comment and continue to seek ways to increase the utility of the information collection as our limited resources permit. At the same time, the comment did not suggest we revise the burden we attribute to the associated information collection activity.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Form No. [2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cosmetics	FDA 3613d	113	3	339	0.5 (30 minutes)	170
Food	FDA 3613e, 3613k	468	9	4,212	0.5 (30 minutes)	2,106
Total						2,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via FDA Industry Systems.

Based on a review of the information collection since our last OMB approval, we have reduced our burden estimate. The burden estimate has been lowered due to a reduced number of respondents. We base our estimates on our experience with certificate applications received in the past 3 fiscal years.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14650 Filed 7–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–Z–0025]

Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal

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

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services (Department or HHS) is announcing the withdrawal of a notice published in the **Federal Register** on January 21, 2021, entitled ''Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation.'' HHS also withdraws the requests for proposals issued on its website on September 24, 2020, and revised on January 13, 2021, and ends the period for submission of proposals in response to the requests for proposals.

DATES: The notice published in the **Federal Register** on January 21, 2021, at 86 FR 6343, is withdrawn as of July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993, 301–796–1054.

SUPPLEMENTARY INFORMATION: On September 24, 2020, HHS issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs (collectively, the RFPs) and posted related ''Frequently Asked Questions'' documents (FAQs) on its website. On January 21, 2021, HHS published a notice in the **Federal Register** entitled ''Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation'' (the HHS Notice) (86 FR 6343). The HHS Notice referred to revised versions

of the RFPs. The responses to the RFPs were directed in the HHS Notice and in the RFP for Personal Prescription Drug Importation issued on September 24, 2020, and revised on January 13, 2021, to be submitted to an HHS email address: *import@hhs.gov,* while the RFP for Insulin Reimportation Programs issued on September 24, 2020, and revised on January 13, 2021, directed that responses be sent to *import@hhs.gov* and to the Director of the FDA Import Division in the region of the intended port of entry. The Department is not aware that any proposals were received in response to the HHS Notice or RFPs. The HHS Notice, RFPs, and FAQs are withdrawn. All website statements and other informal issuances with respect to the HHS Notice and RFPs are also withdrawn. Accordingly, no proposals submitted to HHS or FDA in response to the HHS Notice or RFPs on or after July 9, 2021 will be considered by HHS or FDA. HHS intends to consider alternatives to the RFPs.

Dated: June 11, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: June 28, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–14637 Filed 7–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0025]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 9, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0721. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

OMB Control Number 0910–0721—Extension

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue regulations concerning animal food. Specifically, section 403(i) of the FD&C Act (21 U.S.C. 343(i)) requires that certified color additives used in or on a food must be declared by their common or usual names and not be designated by the collective term ''colorings.'' Our regulations in part 501 (21 CFR part 501) set forth the requirements for animal food labeling. Under § 501.22(k)(21 CFR 501.22(k)), animal food manufacturers must declare on the animal food label the presence of certified and noncertified color additives in their animal food products. Our animal food labeling regulation at § 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels. The purpose of the labeling is to provide animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable about the foods they purchase for their animals. Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.

In the **Federal Register** of March 4, 2021 (86 FR 12690), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received 22 comments expressing the importance of color additive information on pet food labeling, along with other ingredient disclosures. FDA appreciates these comments; at this time, we are not revising the regulations found at § 501.22(k) related to color additive information on the labeling of animal food.

FDA estimates the burden of this collection of information as follows:

Description of Respondents: Respondents to this collection of information are manufacturers of pet food products that contain color additives.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.	3,120	0.8292	2,587	0.25 (15 minutes)	647

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14655 Filed 7–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1944]

Determination of Regulatory Review Period for Purposes of Patent Extension; AJOVY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AJOVY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 7, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 5, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 7, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 7, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–E–1944 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AJOVY.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and

an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product AJOVY (fremanezumab-vfrm). AJOVY is indicated for the preventive treatment of migraine in adults. Subsequent to this approval, the USPTO received a patent term restoration application for AJOVY (U.S. Patent No. 8,007,794) from Teva Pharmaceuticals International GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of AJOVY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AJOVY is 3,216 days. Of this time, 2,882 days occurred during the testing phase of the regulatory review period, while 334 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* November 26, 2009. The applicant claims November 19, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 26, 2009, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 16, 2017. FDA has verified the applicant's claim that the biologics license application (BLA) for AJOVY (BLA 761089) was initially submitted on October 16, 2017.

3. *The date the application was approved:* September 14, 2018. FDA has verified the applicant's claim that BLA 761089 was approved on September 14, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,454 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14652 Filed 7–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodevelopmental and Neurological Disorders.

Date: August 3, 2021.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Eye Disease and Infections.

Date: August 5, 2021.

Time: 11:00 a.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 (Virtual Meeting).

Contact Person: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205, MSC 7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cognitive and Neuropathological Signatures of Alzheimer's Disease, Brain Injury and Aging.

Date: August 5, 2021.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701

Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

(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: July 2, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–14617 Filed 7–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-Day Comment Request: Generic Clearance To Collect Stakeholder Feedback on the Research Domain Criteria (RDoC) Initiative, (NIMH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Andrew Hooper, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call (301) 480–8433, or email your request, including your mailing address, to *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 5, 2021, pages 23974–23975 (Vol. 86, No. 85) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: Generic Clearance to Collect Stakeholder Feedback on the Research Domain Criteria (RDoC) Initiative, 0925–0756, EXTENSION, exp., date 07/31/2021, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: This request serves as notice that the National Institute of Mental Health (NIMH) plans to collect stakeholder feedback to assess the strengths and weaknesses of the Research Domain Criteria (RDoC) initiative. NIMH launched RDoC in 2009 to implement Strategy 1.4 of the 2008 NIMH Strategic Plan: ''Develop new ways of classifying disorders based on dimensions of observable behaviors and brain functions.'' Rather than beginning with a syndrome and then working ''down'' to clarify mechanisms, the aim of RDoC is to guide research that begins with disruptions in neurobiological and behavioral mechanisms, and then works across systems to clarify connections among such disruptions and clinical symptoms. NIMH has developed social media platforms and tools for the RDoC initiative, including a dedicated RDoC twitter account (*https://twitter.com/nimh_rdoc*), the RDoC website, which also houses the RDoC matrix (*https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml*), and several educational and training resources (including webinars) to educate the field and interface with scientists who may have questions about RDoC (*https://www.nimh.nih.gov/research-priorities/rdoc/rdoc-educational-and-training-resources.shtml*). The evaluation approach will be conducted using surveys centered around current content (*i.e.,* website, twitter, and webinars), as well as open ended surveys that will cover the scientific content of RDoC. The information collected will be used by NIMH staff to determine success of the RDoC initiative, develop future directions and endeavors, and to help guide programmatic priorities for RDoC and the Institute.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 490.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Workshops	50	1	8	400
Interviews	10	1	30/60	5
Surveys	100	1	30/60	50
Focus Groups	10	1	1	10
Assessment Forms	100	1	15/60	25
Total	270	270		490

Dated: July 6, 2021.

Andrew A. Hooper,

Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2021–14630 Filed 7–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. ICEB–2021–0007]

RIN 1653–ZA19

Employment Authorization for Yemeni F–1 Students Experiencing Severe Economic Hardship as a Direct Result of the Current Crisis in Yemen

AGENCY: U.S. Immigration and Customs Enforcement (ICE), Department of Homeland Security (DHS).

SUMMARY: This notice announces that the Secretary of Homeland Security (Secretary) is suspending certain regulatory requirements for F–1 nonimmigrant students whose country of citizenship is Yemen (regardless of country of birth) and who are experiencing severe economic hardship as a direct result of the current crisis in Yemen.

The Secretary is taking action to provide relief to Yemeni citizens who are lawful F–1 nonimmigrant students so the students may request employment authorization, work an increased number of hours while school is in session, and reduce their course load while continuing to maintain F–1 nonimmigrant student status. DHS will deem an F–1 nonimmigrant student who receives employment authorization by means of this notice to be engaged in a ''full course of study'' for the duration of the employment authorization, if the nonimmigrant student satisfies the minimum course load requirement described in this notice.

DATES: This notice will be effective on September 4, 2021 and will remain in effect through March 3, 2023.

FOR FURTHER INFORMATION CONTACT: Sharon Snyder, Unit Chief, Policy and Response Unit, Student and Exchange Visitor Program; U.S. Immigration and Customs Enforcement, 500 12th Street SW, Stop 5600, Washington, DC 20536–5600; email: *sevp@ice.dhs.gov,* telephone: (703) 603–3400. This is not a toll-free number. Program information is available at *http://www.ice.gov/sevis/.*

SUPPLEMENTARY INFORMATION:

What action is DHS taking under this notice?

The Secretary is exercising authority under 8 CFR 214.2(f)(9) to temporarily suspend the applicability of certain requirements governing on-campus and off-campus employment for F–1 nonimmigrant students whose country of citizenship is Yemen who are present in the United States in lawful F–1 nonimmigrant student status as of September 4, 2021, and who are experiencing severe economic hardship as a direct result of the current crisis in Yemen. Suspension of the employment limitations will be available from September 4, 2021 until March 3, 2023, for those who are in lawful F–1 nonimmigrant status as of September 4, 2021. DHS will deem an F–1 nonimmigrant student granted employment authorization by means of this notice to be engaged in a ''full course of study'' for the duration of the employment authorization, if the F–1 nonimmigrant student satisfies the minimum course load set forth in this notice.[1] *See* 8 CFR 214.2(f)(6)(i)(F).

Who is covered by this notice?

This notice applies exclusively to F–1 nonimmigrant students who meet all of the following conditions:

(1) Are citizens of Yemen (regardless of country of birth);

(2) Are lawfully present in the United States in an F–1 nonimmigrant status on September 4, 2021, under section 101(a)(15)(F)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1101(a)(15)(F)(i);

(3) Are enrolled in an academic institution that is Student and Exchange Visitor Program (SEVP)-certified for enrollment of F–1 nonimmigrant students;

(4) Are currently maintaining F–1 nonimmigrant status; and

(5) Are experiencing severe economic hardship as a direct result of the current crisis in Yemen.

This notice applies to F–1 nonimmigrant students in an approved private school in grades kindergarten through grade 12, public school in grades 9 through 12, and undergraduate and graduate education. An F–1 nonimmigrant student covered by this notice who transfers to another SEVP-certified academic institution remains eligible for the relief provided by means of this notice.

Why is DHS taking this action?

DHS initially designated Yemen for Temporary Protected Status (TPS) on September 3, 2015, based on ongoing armed conflict in the country resulting from the July 2014 offensive by the Houthis, a northern opposition group that initiated a violent, territorial expansion across the country, eventually forcing the Yemeni government leaders into exile in Saudi Arabia.[2]

As a result of the ongoing armed conflict and continuous crisis in Yemen, the Secretary has redesignated and extended TPS for Yemen for 18 months, effective September 4, 2021. Consistent with USCIS designation for TPS for Yemen, this notice provides relief to Yemeni F–1 nonimmigrant students experiencing severe economic hardship as a direct result of the crisis in Yemen. DHS has reviewed conditions in Yemen and determined that making employment authorization available for eligible nonimmigrant students is warranted. This notice will enable Yemeni F–1 nonimmigrant students to request employment authorization, carry a reduced course load, and increase the number of authorized hours for employment.

The civil war in Yemen has entered its eighth year, killing an estimated 233,000 individuals.[3] The United Nations High Commissioner for Refugees (UNHCR) has recorded 69,160 Yemeni refugees and asylum-seekers in neighboring countries.[4] Over 4 million people have been internally displaced within Yemen, and 166,000 of those

[1] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 3, 2023, provided the student satisfies the minimum course load requirement in this notice. DHS also considers students who engage in online coursework pursuant to ICE coronavirus disease 2019 (COVID–19) guidance for nonimmigrant students to be in compliance with regulations while such guidance remains in effect. See ICE Guidance and Frequently Asked Questions on COVID–19, available at *https://www.ice.gov/coronavirus* [last visited May 2021].

[2] USCIS *DHS Announces Temporary Protected Status Designation for Yemen,* available at: *https://www.uscis.gov/archive/dhs-announces-temporary-protected-status-designation-for-yemen* [last visited May 2021].

[3] United Nations News *UN humanitarian office puts Yemen war dead at 233,000, mostly from 'indirect causes' available at https://news.un.org/en/story/2020/12/1078972#:~:text=UN%20Podcasts-,UN%20humanitarian%20office%20puts%20Yemen%20war%20dead,%2C%20mostly%20from%20'indirect%20causes'&text=Millions%20of%20children%20across%20Yemen,lack%20of%20basic%20health%20services* [last visited May 2021].

[4] United Nations High Commissioner for Refugees (UNHCR) *Refugee Data Finder 2015–2020 available at https://www.unhcr.org/refugee-statistics/download/?url=Gb4fe1* [last visited May 2021].

were displaced in 2020.[5] Even if a political resolution to the conflict is reached, Yemen will be faced with tremendous reconstruction needs.

Yemen's civil war has caused a wide range of emergencies, including: Economic contraction, deepening poverty, high levels of food insecurity, a severely weakened medical system, the reappearance or increased incidence of certain communicable diseases, a collapse in basic services such as water, electricity, and fuel shortages, and institutional and political tensions. Additionally, the impact of the COVID–19 pandemic further devastated what remained of Yemen's healthcare infrastructure after years of protracted conflict. There are 24.1 million people (approximately 80% of the population) in need of humanitarian assistance as a result of civil war and conflict in Yemen.[6] The United Nations International Children's Emergency Fund (UNICEF) estimates that 18 million people in Yemen (approximately 59% of the population) do not currently have access to clean water and sanitation.[7]

As of May 23, 2021, 309 F–1 nonimmigrant students whose country of citizenship is Yemen were physically present the United States and enrolled in SEVP-certified academic institutions. Given the extent of the crisis in Yemen, affected F–1 nonimmigrant students whose primary means of financial support comes from Yemen may need to be exempt from the normal student employment requirements to continue studying in the United States. The current crisis has created financial barriers for F–1 nonimmigrant students to support themselves and return to Yemen for the foreseeable future. Without employment authorization, these students may lack the means to meet basic living expenses.

What is the minimum course load requirement set forth in this notice?

Undergraduate F–1 nonimmigrant students who receive on-campus or off-campus employment authorization under this notice must remain registered for a minimum of six semester or quarter hours of instruction per academic term.[8] A graduate-level F–1 nonimmigrant student who receives on-campus or off-campus employment authorization under this notice must remain registered for a minimum of three semester or quarter hours of instruction per academic term. *See* 8 CFR 214.2(f)(5)(v).

In addition, an F–1 nonimmigrant student (either undergraduate or graduate) granted on campus or off-campus employment authorization under this notice may count up to the equivalent of one class or three credits per session, term, semester, trimester, or quarter of online or distance education toward satisfying this minimum course load requirement, unless the course of study is in a language study program.[9] *See* 8 CFR 214.2(f)(6)(i)(G). An F–1 nonimmigrant student who attends an approved private school in grades kindergarten through grade 12 or public school in grades 9 through 12, must maintain ''class attendance for no less than the minimum number of hours a week prescribed by the school for normal progress toward graduation,'' as required under 8 CFR 214.2(f)(6)(i)(E).

May an eligible F–1 nonimmigrant student who already has on-campus or off-campus employment authorization benefit from the suspension of regulatory requirements under this notice?

Yes. A Yemeni F–1 nonimmigrant student who already has on-campus or off-campus employment authorization and is otherwise eligible may benefit under this notice, which suspends regulatory requirements relating to the minimum course load requirement under 8 CFR 214.2(f)(6)(i)(A) and (B) and the employment eligibility requirements under 8 CFR 214.2(f)(9) as specified in this notice. Such an eligible F–1 nonimmigrant student may benefit without having to apply for a new Form I–766, Employment Authorization Document (EAD). To benefit from this notice, the F–1 nonimmigrant student must request the designated school official (DSO) enter the following statement in the remarks field of the student's Student and Exchange Visitor Information System (SEVIS) record, which the student's Form I–20, Certificate of Eligibility for Nonimmigrant (F–1) Student Status, will reflect:

> Approved for more than 20 hours per week of [DSO must insert ''on-campus'' or ''off-campus,'' depending upon the type of employment authorization the student already has] employment authorization and reduced course load under the Special Student Relief authorization from [DSO must insert the beginning date of the notice or the beginning date of the student's employment, whichever date is later] until [DSO must insert either the student's program end date, the current EAD expiration date (if the student is currently authorized for off-campus employment), or the end date of this notice, whichever comes first].

Must the F–1 nonimmigrant student apply for reinstatement after expiration of this special employment authorization if the student reduces his or her ''full course of study''?

No. DHS will deem an F–1 nonimmigrant student who receives and comports with the employment authorization permitted under this notice to be engaged in a ''full course of study'' for the duration of the student's employment authorization, provided that a qualifying undergraduate level F–1 nonimmigrant student remains registered for a minimum of six semester or quarter hours of instruction per academic term and a qualifying graduate level F–1 nonimmigrant student remains registered for a minimum of three semester or quarter hours of instruction per academic term.[10] *See* 8 CFR 214.2(f)(5)(v) and (f)(6)(i)(F). DHS will not require such students to apply for reinstatement under 8 CFR 214.2(f)(16) if otherwise maintaining F–1 nonimmigrant student status.

Will an F–2 dependent (spouse or minor child) of an F–1 nonimmigrant student covered by this notice be eligible to apply for employment authorization?

No. An F–2 spouse or minor child of an F–1 nonimmigrant student cannot be authorized to work in the United States and, therefore, may not accept employment under the F–2 nonimmigrant status. *See* 8 CFR 214.2(f)(15)(i).

[5] UNHCR *Operational Update: Yemen,* April 15, 2021 *available at https://reporting.unhcr.org/sites/default/files/UNHCR%20Yemen%20Operational%20Update%20-%2015%20April%202021.pdf* [last visited May 2021].

[6] The United Nations, *The United Nations in Yemen available at https://yemen.un.org/en/about/about-the-un,* [last visited May 2021].

[7] UNICEF Yemen, *Water, Sanitation, Hygiene, available at https://www.unicef.org/yemen/water-sanitation-and-hygiene* [last visited May 2021].

[8] Undergraduate F–1 students enrolled in a term of different duration must register for at least one half of the credit hours normally required under a ''full course of study.'' *See* 8 CFR 214.2(f)(6)(i)(B).

[9] DHS also considers students who engage in online coursework pursuant to ICE coronavirus disease 2019 (COVID–19) guidance for nonimmigrant students to be in compliance with regulations while such guidance remains in effect. See ICE Guidance and Frequently Asked Questions on COVID–19, available at *https://www.ice.gov/coronavirus* [last visited May 2021].

[10] Undergraduate F–1 nonimmigrant students enrolled in a term of different duration must register for at least one half of the credit hours normally required under a ''full course of study.'' *See* 8 CFR 214.2(f)(6)(i)(B).

Will the suspension of the applicability of the standard student employment requirements apply to an individual who receives an initial F–1 visa and makes an initial entry in the United States after September 4, 2021?

No. The suspension of the applicability of the standard regulatory requirements only applies to those F–1 nonimmigrant students who meet the following conditions:

(1) Are citizens of Yemen, regardless of country of birth;

(2) Are lawfully present in the United States in F–1 nonimmigrant status on September 4, 2021, under section 101(a)(15)(F)(i) of the INA, 8 U.S.C. 1101(a)(15)(F)(i);

(3) Are enrolled in an academic institution that is SEVP-certified for enrollment for F–1 nonimmigrant students;

(4) Are currently maintaining F–1 nonimmigrant status; and

(5) Are experiencing severe economic hardship as a direct result of the current crisis in Yemen.

An F–1 nonimmigrant student who does not meet all of these requirements is ineligible for the suspension of the applicability of the standard regulatory requirements (even if experiencing severe economic hardship as a direct result of the current crisis in Yemen).

Does this notice apply to a continuing F–1 nonimmigrant student who departs the United States after September 4, 2021 and who needs to obtain a new F–1 visa before returning to the United States to continue an educational program?

Yes. This notice applies to such a nonimmigrant student, but only if the DSO has properly notated the SEVIS record, which will then appear on the student's Form I–20. The normal rules for visa issuance remain applicable to a nonimmigrant who needs to apply for a new F–1 visa to continue an educational program in the United States.

Does this notice apply to elementary school, middle school, and high school students in F–1 status?

Yes. However, this notice does not by itself reduce the required course load for F–1 nonimmigrant students enrolled in kindergarten through grade 12 at a private school or grades 9 through 12 at a public school. Such Yemeni nonimmigrant students must maintain the minimum number of hours of class attendance per week prescribed by the academic institution for normal progress toward graduation. *See* 8 CFR 214.2(f)(6)(i)(E). The suspension of certain regulatory requirements related to employment through this notice is applicable to all eligible F–1 nonimmigrant students regardless of educational level. Thus, eligible F–1 nonimmigrant students from Yemen enrolled in an elementary school, middle school, or high school do benefit from the suspension of the requirement in 8 CFR 214.2(f)(9)(i) that limits on-campus employment to 20 hours per week while school is in session. Nothing in this notice affects the applicability of federal and state labor laws limiting the employment of minors.

On-Campus Employment Authorization

Will an F–1 nonimmigrant student who receives on-campus employment authorization under this notice have authorization to work more than 20 hours per week while school is in session?

Yes. For an F–1 nonimmigrant student covered in this notice, the Secretary is suspending the applicability of the requirement in 8 CFR 214.2(f)(9)(i) that limits an F–1 student's on-campus employment to 20 hours per week while school is in session. An eligible nonimmigrant student has authorization to work more than 20 hours per week while school is in session, if the DSO has entered the following statement in the remarks field of the SEVIS student record, which will appear on the student's Form I–20:

> Approved for more than 20 hours per week of on-campus employment and reduced course load, under the Special Student Relief authorization from [DSO must insert the beginning date of the notice or the beginning date of the students employment, whichever date is later] until [DSO must insert the student's program end date or the end date of the notice, whichever date comes first].

To obtain on-campus employment authorization, the F–1 nonimmigrant student must demonstrate to the DSO that the employment is necessary to avoid severe economic hardship directly resulting from the current crisis in Yemen. A nonimmigrant student authorized by the DSO to engage in on-campus employment by means of this notice does not need to file any applications with U.S. Citizenship and Immigration Services (USCIS). The standard rules permitting full-time employment on-campus when school is not in session or during school vacations apply. *See* 8 CFR 214.2(f)(9)(i).

Will an F–1 nonimmigrant student who receives on-campus employment authorization under this notice have authorization to reduce the normal course load and still maintain his or her F–1 student status?

Yes. DHS will deem an F–1 nonimmigrant student who receives on-campus employment authorization under this notice to be engaged in a ''full course of study'' for the purpose of maintaining F–1 student status for the duration of the on-campus employment, if the student satisfies the minimum course load requirement described in this notice. *See* 8 CFR 214.2(f)(6)(i)(F). However, the authorization to reduce the normal course load is solely for DHS purposes of determining valid F–1 nonimmigrant student status. Nothing in this notice mandates that school officials allow an F–1 student to take a reduced course load if the reduction would not meet the school's minimum course load requirement for continued enrollment.[11]

Off-Campus Employment Authorization

What regulatory requirements does this notice temporarily suspend relating to off-campus employment?

For an F–1 student covered by this notice, as provided under 8 CFR 214.2(f)(9)(ii)(A), the Secretary is suspending the following regulatory requirements relating to off-campus employment:

(a) The requirement that a student must have been in F–1 nonimmigrant student status for one full academic year to be eligible for off-campus employment;

(b) The requirement that an F–1 nonimmigrant student must demonstrate that acceptance of employment will not interfere with the student's carrying a full course of study;

(c) The requirement that limits an F–1 nonimmigrant student's employment authorization to no more than 20 hours per week of off-campus employment while school is in session; and

(d) The requirement that the student demonstrate that employment under 8 CFR 214.2(f)(9)(i) is unavailable or otherwise insufficient to meet the needs that have arisen as a result of the unforeseen circumstances.

[11] Minimum course load requirement for enrollment in a school must be established in a publicly available document (*e.g.,* catalog, website, or operating procedure), and it must be a standard applicable to all students (U.S. citizens and foreign students) enrolled at the school.

Will an F–1 nonimmigrant student who receives off-campus employment authorization under this notice have authorization to reduce the normal course load and still maintain F–1 nonimmigrant status?

Yes. DHS will deem an F–1 nonimmigrant student who receives off-campus employment authorization by means of this notice to be engaged in a ''full course of study'' for the purpose of maintaining F–1 nonimmigrant student status for the duration of the students' employment authorization if the student satisfies the minimum course load requirement described in this notice. *See* 8 CFR 214.2(f)(6)(i)(F). However, the authorization to reduce the normal course load is solely for DHS purposes of determining valid F–1 student status. Nothing in this notice mandates that school officials allow an F–1 nonimmigrant student to take a reduced course load if such a reduced course load would not meet the school's minimum course load requirement.[12]

How may an eligible F–1 nonimmigrant student obtain employment authorization for off-campus employment with a reduced course load under this notice?

An F–1 nonimmigrant student must file a Form I–765, Application for Employment Authorization, with USCIS to apply for off-campus employment authorization based on the severe economic hardship directly resulting from the crisis in Yemen. Filing instructions are at *http://www.uscis.gov/i-765.*

Fee considerations. Submission of a Form I–765 currently requires payment of a $410 fee. An applicant who is unable to pay the fee may submit a completed Form I–912, Request for Fee Waiver, along with the Form I–765 Application for Employment Authorization. *See www.uscis.gov/feewaiver.* The submission must include an explanation of why USCIS should grant the fee waiver and the reason(s) for the inability to pay, and any evidence to support the reason(s). *See* 8 CFR 103.7(c).

Supporting documentation. An F–1 nonimmigrant student seeking off-campus employment authorization due to severe economic hardship must demonstrate the following to the DSO:

(1) This employment is necessary to avoid severe economic hardship; and

(2) The hardship is a direct result of the current crisis in Yemen.

If the DSO agrees that the F–1 nonimmigrant student should receive such employment authorization, the DSO must recommend application approval to USCIS by entering the following statement in the remarks field of the student's SEVIS record, which will then appear on that student's Form I–20:

> Recommended for off-campus employment authorization in excess of 20 hours per week and reduced course load under the Special Student Relief authorization from the date of the USCIS authorization noted on Form I–766 until [DSO must insert the student's program end date or the end date of the notice, whichever date comes first].

The F–1 nonimmigrant student must then file the properly endorsed Form I–20 and Form I–765 according to the instructions for the Form I–765. The F–1 nonimmigrant student may begin working off campus only upon receipt of the EAD from USCIS.

DSO recommendation. In making a recommendation that a nonimmigrant student be approved for Special Student Relief, the DSO certifies the following:

(a) The F–1 nonimmigrant student is in good academic standing and carrying a ''full course of study'' [13] at the time of the request for employment authorization;

(b) The F–1 nonimmigrant student is a citizen of Yemen and is experiencing severe economic hardship as a direct result of the current crisis in Yemen, as documented on the Form I–20;

(c) The F–1 nonimmigrant student has confirmed that the student will comply with the reduced course load requirements of 8 CFR 214.2(f)(5)(v) and register for the duration of the authorized employment for a minimum of six semester or quarter hours of instruction per academic term if at the undergraduate level or for a minimum of three semester or quarter hours of instruction per academic term if at the graduate level; and

(d) The off-campus employment is necessary to alleviate severe economic hardship to the individual as a direct result of the current humanitarian crisis in Yemen.

Processing. To facilitate prompt adjudication of the student's application for off-campus employment authorization under 8 CFR 214.2(f)(9)(ii)(C), the F–1 nonimmigrant student should do both of the following:

(a) Ensure that the application package includes all of the following documents:

(1) A completed Form I–765;

(2) The required fee or properly documented fee waiver request as defined in 8 CFR 103.7(c); and

(3) A signed and dated copy of the student's Form I–20 with the appropriate DSO recommendation, as previously described in this notice; and

(b) Send the application in an envelope that is clearly marked on the front of the envelope, bottom right-hand side, with the phrase ''SPECIAL STUDENT RELIEF.'' Failure to include this notation may result in significant processing delays.

If USCIS approves the student's Form I–765, USCIS will send the student an EAD as evidence of employment authorization. The EAD will contain an expiration date that does not exceed the end of the granted temporary relief.

Temporary Protected Status (TPS) Considerations

Can an F–1 nonimmigrant student apply for TPS and for benefits under this notice at the same time?

Yes. An F–1 nonimmigrant student who has not yet applied for TPS or other relief that reduce the student's course load per term and permits an increase number of work hours per week, such as the Special Student Relief,[14] under this notice has two options.

Under the first option, the nonimmigrant student may file the TPS application according to the instructions in the **Federal Register** Notice designating Yemen for TPS. All TPS applicants must file a Form I–821, *Application for Temporary Protected Status.* Although not required to do so, if an F–1 nonimmigrant student wants to obtain an EAD based on the student's TPS application valid until March 3, 2023, and to be eligible for EAD extensions that may be available to EADs with an A–12 or C–19 category code, the student must file Form I–765 and pay the Form I–765 fee (or submit a Form I–912, Request for a Fee Waiver). After receiving the TPS-related EAD, an F–1 nonimmigrant student may request that the student's DSO make the required entry in SEVIS, issue an updated Form I–20, as described in this notice, and notate that the nonimmigrant student has been authorized to carry a reduced course load and is working pursuant to a TPS-related EAD. So long as the nonimmigrant student maintains the minimum course load described in this notice, does not otherwise violate the student's nonimmigrant status,

[12] Minimum course load requirement for enrollment in a school must be established in a publicly available document (*e.g.,* catalog, website, or operating procedure), and it must be a standard applicable to all students (U.S. citizens and foreign students) enrolled at the school.

[13] *See* 8 CFR 214.2(f)(6).

[14] DHS Study in the States, Special Student Relief *available at https://studyinthestates.dhs.gov/students/special-student-relief* [last visited May 2021].

including as provided under 8 CFR 214.1(g), and maintains the student's TPS, then the student maintains F–1 status and TPS concurrently.

Under the second option, the nonimmigrant student may apply for an EAD under Special Student Relief by filing the Form I–765 with the location specified in the filing instructions. At the same time, the F–1 nonimmigrant student may file a separate TPS application, but must submit the TPS application according to the instructions provided in the **Federal Register** Notice designating Yemen for TPS. If the nonimmigrant student has already applied for employment authorization under student relief, they are not required to submit the Form I–765 as part of the TPS application. However, some nonimmigrant students may wish to obtain a TPS EAD in light of certain extensions that may be available to EADs with an A–12 or C–19 category code. The nonimmigrant student should check the appropriate box when filling out Form I–821 to request a TPS-related EAD. Again, the nonimmigrant student will be able to maintain compliance requirements for F–1 nonimmigrant student status while having TPS.

When a student applies simultaneously for TPS status and benefits under this notice, what is the minimum course load requirement while an application for employment authorization is pending?

The F–1 nonimmigrant student must maintain normal course load requirements for a ''full course of study'' [15] unless or until the nonimmigrant student receives employment authorization under this notice. TPS-related employment authorization, by itself, does not authorize a nonimmigrant student to drop below twelve credit hours, or otherwise applicable minimum requirements (*e.g.,* clock hours for language students). Once approved for Special Student Relief employment authorization, the F–1 nonimmigrant student may drop below twelve credit hours, or otherwise applicable minimum requirements (with a minimum of six semester or quarter hours of instruction per academic term if the student is at the undergraduate level, or a minimum of three semester or quarter hours of instruction per academic term if the student is at the graduate level). *See* 8 CFR 214.2(f)(5)(v), 214.2(f)(6), 214.2(f)(9)(i) and (ii).

[15] *See* 8 CFR 214.2(f)(6).

How does a student who has received a TPS-related employment authorization document then apply for authorization to take a reduced course load under this notice?

There is no further application process if a student has been approved for a TPS-related EAD. However,the F–1 nonimmigrant student must demonstrate and provide documentation to the DSO of the direct economic hardship resulting from the civil unrest in Yemen. The DSO will then verify and note this in the student's SEVIS record to enable the F–1 nonimmigrant student with TPS to reduce their course load without any further action or application. No other EAD needs to be issued for the F–1 nonimmigrant student to have employment authorization.

Can a noncitizen who has been granted TPS apply for reinstatement to F–1 student status after his or her F–1 status has lapsed?

Yes. Current regulations permit certain students who fall out of F–1 nonimmigrant student status to apply for reinstatement. *See* 8 CFR 214.2(f)(16). This provision might apply to a student who worked on a TPS-related EAD or dropped their course load before publication of this notice, and therefore fell out of student status. The student must satisfy the criteria set forth in the student status reinstatement regulations.

How long will this notice remain in effect?

This notice grants temporary relief until March 3, 2023,[16] to eligible F–1 nonimmigrant students. DHS will continue to monitor the situation in Yemen. Should the special provisions authorized by this notice need modification or extension, DHS will announce such changes in the **Federal Register**.

[16] Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a ''full course of study,'' see 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 3, 2023, provided the student satisfies the minimum course load requirement in this notice. DHS also considers students who engage in online coursework pursuant to ICE coronavirus disease 2019 (COVID–19) guidance for nonimmigrant students to be in compliance with regulations while such guidance remains in effect. See ICE Guidance and Frequently Asked Questions on COVID–19, available at *https://www.ice.gov/coronavirus* [last visited May 2021].

Paperwork Reduction Act (PRA)

An F–1 nonimmigrant student seeking off-campus employment authorization due to severe economic hardship must demonstrate to the DSO that this employment is necessary to avoid severe economic hardship. A DSO who agrees that a nonimmigrant student should receive such employment authorization must recommend an application approval to USCIS by entering information in the remarks field of the student's SEVIS record. The authority to collect this information is in the SEVIS collection of information currently approved by the Office of Management and Budget (OMB) under OMB Control Number 1653–0038.

This notice also allows eligible F–1 nonimmigrant students to request employment authorization, work an increased number of hours while the academic institution is in session, and reduce the student's course load while continuing to maintain F–1 nonimmigrant student status.

To apply for employment authorization, certain F–1 nonimmigrant students must complete and submit a currently approved Form I–765 according to the instructions on the form. OMB has previously approved the collection of information contained on the current Form I–765, consistent with the PRA (OMB Control No. 1615–0040). Although there will be a slight increase in the number of Form I–765 filings because of this notice, the number of filings currently contained in the OMB annual inventory for Form I–765 is sufficient to cover the additional filings. Accordingly, there is no further action required under the PRA.

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2021–14676 Filed 7–7–21; 4:15 pm]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control Number 1653–NEW]

Agency Information Collection Activities: New Collection: Flight Manifest/Billing Agreement

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

ACTION: 30-Day notice.

SUMMARY: In accordance with the Paperwork Reductions Act (PRA) of

1995, U.S. Immigration and Customs Enforcement (ICE), the Department of Homeland Security (DHS), will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance. This information collection was previously published in the **Federal Register** on April 27, 2021, allowing for a 60-day comment period. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until August 9, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of the 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: For specific questions related to collection activities, please contact Lois J. Burrows, Office of the Chief Financial Officer, 202–732–4812, email: *lois.j.burrows@ice.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Flight Manifest/Billing Agreement.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. The Flight Manifest/Billing Agreement collects information for the purpose of confirming Space Available passengers on any ICE-chartered flight and to facilitate the effective billing of those passengers for the full coach fare of their seats on the flight.

(5) *An estimate of the total number of respondents:* The estimated total number of respondents for this information collection is 250 and the estimated hour burden per response is .25 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual burden is 63 hours.

Dated: July 6, 2021.

Scott Elmore,

PRA Clearance Officer.

[FR Doc. 2021–14633 Filed 7–8–21; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2014–0001]

TSA PreCheck® Application Program Fees

AGENCY: Transportation Security Administration, DHS.

ACTION: Notice.

SUMMARY: The Transportation Security Administration (TSA) administers the TSA PreCheck® Application Program (also known as the TSA Pre✓® Application Program), in which members of the public may apply to be eligible for expedited airport security screening. To apply for TSA PreCheck Application Program eligibility, individuals voluntarily provide biometric and biographic information that TSA uses to conduct a security threat assessment and those applicants pay a fee to cover the cost to operate the TSA PreCheck Application Program. In this Notice, TSA announces the anticipated launch of additional enrollment providers who will be able to establish additional price points for the TSA PreCheck Application Program. These enrollment providers are planned to become available in 2021 to increase opportunities to apply for membership in the program. TSA will announce the details and pricing for these new enrollment options, when available, via *https://www.tsa.gov/precheck.*

DATES: This notice is applicable July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Anne Walbridge, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6047; 571–227–2329; or email at *TSAPrecheckEnrollment@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Availability of Notice Document

You can get an electronic copy of published documents through the internet by—

(1) Searching the electronic Federal Docket Management System (FDMS) web page at *http://www.regulations.gov;* or

(2) Accessing the Government Publishing Office's web page at *http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR* to view the daily published **Federal Register** edition; or accessing the ''Search the **Federal Register** by Citation'' in the ''Related Resources'' column on the left, if you need to do a Simple or Advanced search for information, such as a type of document that crosses multiple agencies or dates.

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section.

I. Summary

The TSA PreCheck Application Program (TSA PreCheck) is a voluntary, expedited security screening program connecting low-risk travelers departing from the United States with smarter security and a better air travel experience.[1] There are approximately 10 million members in the TSA PreCheck Application Program. Individuals enrolled in the TSA PreCheck Application Program are eligible to receive expedited screening at U.S. airports. As explained in the December 4, 2013 Notice in the **Federal Register**,[2] membership in the TSA PreCheck Application Program is within the sole discretion of TSA. Individuals may also receive TSA PreCheck expedited screening via membership in other programs such as certain U.S. Customs

[1] The TSA PreCheck Application Program refers to the DHS Trusted Traveler Program that TSA operates to determine if individuals are low-risk and may receive expedited screening. TSA PreCheck refers to expedited screening provided by TSA.

[2] *See* Notice, 78 FR 72922 (December 4, 2013).

and Border Protection (CBP) Trusted Traveler Programs. These individuals do not pay a fee to TSA for membership in such other programs.

TSA established the TSA PreCheck Application Program in December 2013 to expand access to expedited screening to individuals who voluntarily provide information that TSA uses to determine whether the traveler is low risk. TSA uses biographic and biometric information the applicant provides to conduct a security threat assessment (STA) that includes review of criminal history, immigration, intelligence, and regulatory violation records. As part of the enrollment process, TSA requires that applicants present government-issued identity documents with a photo to prove their identity. To prepare for REAL ID enforcement, in advance of the REAL ID card-based enforcement deadline, TSA will require new TSA PreCheck applicants as well as renewal applicants to provide a REAL ID-compliant document if enrolling with a state-issued identity document. Applicants must also prove they are a U.S. person as required by the program. Following enrollment, TSA evaluates the information generated by the vetting process to determine whether the individual poses a low risk to transportation and national security. Once completed, the STA remains valid for five years, provided the individual continues to meet the eligibility standards. At the end of the five-year term, individuals wishing to maintain their TSA PreCheck eligibility must renew their membership in the program which includes a new STA.

If TSA determines that the applicant is low risk, TSA issues a Known Traveler Number (KTN) [3] that the individual can use when making flight reservations. Enrollment in the TSA PreCheck Application Program and use of the associated KTN do not guarantee that an individual will receive expedited screening at airport security checkpoints. TSA retains an element of randomness to maintain unpredictability for security purposes, and travelers with valid KTNs may be selected for standard or enhanced physical screening on occasion.

An individual is ineligible for a KTN and thus access to TSA PreCheck expedited screening if TSA determines that the individual poses a risk to transportation or national security; has committed certain criminal acts; [4] does not meet the immigration status standards; [5] has committed regulatory violations; [6] or is otherwise not a low-risk traveler. TSA notifies individuals who it determines are ineligible for a KTN through the TSA PreCheck Application Program in writing, and they continue to undergo standard screening at airport security checkpoints.

TSA is required by law to charge a non-refundable fee to cover the costs of operating the TSA PreCheck Application Program.[7] Collecting biographic and biometric information from applicants, conducting the STA, adjudicating the results of the STA, and managing the program [8] generate costs for TSA, the enrollment provider, and the Federal Bureau of Investigation (FBI). The current initial application and renewal fee for the TSA PreCheck Application Program is $85.00. The fee will remain no more than $85 for individuals enrolling through the Universal Enrollment Services enrollment provider.

II. Discussion of Future Program Adjustments

The TSA PreCheck Application Program is a successful trusted traveler program that improves the travel experience for approximately 10 million travelers. Recent statutory changes aimed at increasing membership in the TSA PreCheck Application Program require TSA to expand the number of companies providing enrollment services. Specifically, section 1937 of the TSA Modernization Act requires TSA to add at least two enrollment vendors to the program.[9] On January 9, 2020, TSA announced that it selected Alclear, LLC; IDEMIA, and; Telos Identity Management Solutions, LLC as enrollment providers as part of a full and open competition posted on FedBizOps. These vendors will be free to compete in the marketplace to offer creative enrollment products using new locations, procedures, systems, and fees to gain program applicants. TSA will review and approve vendor platforms to ensure they meet the latest cybersecurity requirements before a vendor can begin processing applications. Note that TSA, through the Universal Enrollment Services contract, will continue to offer the existing TSA PreCheck Application Program products and fees after the new providers begin to operate. The fee to apply for initial membership and to renew membership in the TSA PreCheck Application Program will not exceed $85 for individuals enrolling through the Universal Enrollment Services enrollment provider.

TSA anticipates that the new enrollment providers will begin enrolling applicants in 2021. Each new enrollment provider will be authorized to establish its own fees to cover the cost of services it provides to applicants. While vendor fees may vary to cover the costs of their enrollment products and services,[10] TSA will continue to collect the TSA component of the fee for all individuals who apply for and renew memberships. Therefore, regardless of the fee each new enrollment provider establishes for its services, the three vendors must continue to remit TSA's component to cover the TSA costs to operate the program. The TSA component recovers the costs to analyze the immigration, terrorism, criminal, and regulatory violation information generated in the checks of the various databases; determine whether applicants have a disqualifying factor or are eligible for the TSA PreCheck Application Program; notify applicants of TSA's determination; issue KTNs to eligible individuals; conduct research and development for innovative enhancements to improve the TSA PreCheck Application Program enrollment and the TSA PreCheck expedited screening experience; and continue to monitor databases and information to confirm that the members remain low risk.

The STA that TSA conducts will cover a term of five years and must be renewed with TSA at the end of that term if an individual wishes to maintain their TSA PreCheck eligibility. Vendors will be permitted to offer shorter duration memberships (*e.g.,* one-year memberships) but must still remit the TSA component fee at initial enrollment to TSA to cover TSA's 5-year costs. If a member allows the membership to lapse for any period of time and subsequently applies for renewal, the vendor must remit the TSA component fee again.

[3] The Known Traveler Number is a component of Secure Flight Passenger Data (SFPD), which is defined in TSA Secure Flight regulations at 49 CFR 1560.3. *See also* the Secure Flight regulations at 49 CFR part 1560.

[4] *See* 49 CFR 1572.103 for the criminal standards that apply to TSA PreCheck applicants.

[5] Individuals who apply for membership in the TSA PreCheck Application Program must be U.S. citizens, U.S. Nationals, or Lawful Permanent Residents.

[6] For instance, an individual who interferes with security screening or brings a weapon to the security checkpoint would be deemed ineligible for TSA PreCheck expedited screening.

[7] *See* 49 U.S.C. 114; § 540 of the DHS appropriations act of 2006, Public Law. 109–90 (119 Stat. 2064, 2088–89, Oct. 18, 2005).

[8] *See* § 540, *Id.*

[9] TSA Modernization Act, Division K—Title I of the FAA Reauthorization Act § 1937, Public Law 115–254, 132 Stat. 3186 (Oct. 5, 2018).

[10] Enrollment providers will be responsible for fees imposed by the FBI.

To attract new applicants to the TSA PreCheck Application Program, an enrollment provider may choose to offer additional services or other incentives to TSA PreCheck applicants, beyond membership in the program, as part of its program fee. For instance, an enrollment provider may offer discounts for travel related products.

TSA will ensure all enrollment options and membership fees are publically available on the TSA website once multiple vendors are operational. Applicants can use this publically available information to choose the enrollment option that best meets their needs based on the enrollment service offerings, convenience of enrollment center locations, pricing, and incentives. TSA will announce the details of these new enrollment options, when available, via *https://www.tsa.gov/precheck.*

Dated: July 1, 2021.

Thomas L. Bush,

Acting Executive Assistant Administrator, Operations Support.

[FR Doc. 2021–14518 Filed 7–8–21; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2690–21; DHS Docket No. USCIS–2015–0005]

RIN 1615–ZB76

Extension and Redesignation of Yemen for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice of Temporary Protected Status extension and redesignation.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is extending the designation of Yemen for Temporary Protected Status (TPS) for 18 months, from September 4, 2021, through March 3, 2023, and redesignating Yemen for 18 months, effective September 4, 2021, through March 3, 2023. The extension allows currently eligible TPS beneficiaries to retain TPS through March 3, 2023, so long as they otherwise continue to meet the eligibility requirements for TPS. The redesignation of Yemen allows additional individuals who have been continuously residing in the United States since July 5, 2021, to obtain TPS, if otherwise eligible. Through this Notice, DHS also sets forth procedures necessary for Yemeni nationals (or individuals having no nationality who last habitually resided in Yemen) either to submit an initial registration application under the redesignation and apply for an Employment Authorization Document (EAD) or, if they already have TPS, to re-register under the extension and to apply for renewal of their EADs with U.S. Citizenship and Immigration Services (USCIS). USCIS will issue new EADs with a March 3, 2023 expiration date to eligible beneficiaries under Yemen's TPS designation who timely reregister and apply for EADs under this extension, or who timely register and apply for EADs under this redesignation.

DATES:

Extension of Designation of Yemen for TPS: The 18-month extension of the TPS designation of Yemen is effective September 4, 2021, and will remain in effect through March 3, 2023. The 60-day re-registration period runs from July 9, 2021 through September 7, 2021. (Note: It is important for re-registrants to timely re-register during this 60-day period and not to wait until their EADs expire.)

Redesignation of Yemen for TPS: The 18-month redesignation of Yemen for TPS is effective September 4, 2021, and will remain in effect through March 3, 2023. The initial registration period for new applicants under the Yemen TPS redesignation begins on July 9, 2021 and will remain in effect through March 3, 2023.[1]

FOR FURTHER INFORMATION CONTACT:

- You may contact Andria Strano, Acting Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746, or by phone at 800–375–5283.
- For further information on TPS, including guidance on the re-registration process and additional information on eligibility, please visit the USCIS TPS web page at *http://www.uscis.gov/tps.* You can find specific information about this extension of Yemen's TPS designation by selecting ''Yemen'' from the menu on the left side of the TPS web page.
- If you have additional questions about TPS, please visit *uscis.gov/tools.* Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you are unable to find your answers there, you may also call our USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).
- Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *http://www.uscis.gov,* or visit the USCIS Contact Center at *uscis.gov/contactcenter.*
- Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA Board of Immigration Appeals
CFR Code of Federal Regulations
DHS U.S. Department of Homeland Security
DOS U.S. Department of State
EAD Employment Authorization Document
FNC Final Nonconfirmation
Form I–765 Application for Employment Authorization
Form I–797 Notice of Action
Form I–821 Application for Temporary Protected Status
Form I–9 Employment Eligibility Verification
Form I–912 Request for Fee Waiver
Form I–94 Arrival/Departure Record

[1] In general, individuals must be given an initial registration period of no less than 180 days to register for TPS, but the Secretary has discretion to provide for a longer registration period. *See* 8 U.S.C. 1254a(c)(1)(A)(iv). Historically, the length of the initial registration period has varied. *Compare* 66 FR 14214 (March 9, 2001) (18-month initial registration period for applicants under TPS designation for El Salvador) *with* 80 FR 36346 (June 24, 2015) (180-day initial registration period for applicants under TPS designation for Nepal). In recent years this period has generally been limited to the statutory minimum of 180 days, although later extensions of the initial registration period have also been announced for some countries. *See, e.g.,* 81 FR 4051 (Jan. 25, 2016) (setting 180-day initial registration period during extension and redesignation of South Sudan for TPS); 78 FR 1866 (Jan. 9, 2013) (setting 180-day initial registration period during extension and redesignation of Sudan for TPS); *but see* 75 FR 39957 (July 13, 2010) (extension of previously announced initial 180-day registration period for Haiti TPS applicants to allow more time for individuals to apply). After evaluating whether to limit the initial registration period for TPS under this new designation of Yemen to the statutory minimum of 180 days, DHS has determined that it will provide the full 18 months of this designation for applicants to file their initial registration Form I–821 and, if desired, Form I–765 to obtain employment authorization documentation. Limiting the initial registration period to 180 days may place a burden on applicants who are unable to timely file but would otherwise be eligible for a grant of TPS. In addition, permitting registration throughout the entirety of the designation period could reduce the operational burden on USCIS, as incoming applications may be spread out over a longer period of time. This extended registration period is both in keeping with the humanitarian purpose of TPS and will better advance the goal of ensuring ''the Federal Government eliminates . . . barriers that prevent immigrants from accessing government services available to them.'' *See Executive Order 14012, Restoring Faith in Our Legal Immigration Systems and Strengthening Integration and Inclusion Efforts for New Americans,* 86 FR 8277.

FR Federal Register
Government—U.S. Government
IER—U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section
IJ—Immigration Judge
INA—Immigration and Nationality Act
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
U.S.C.—United States Code

Through this Notice, DHS sets forth procedures necessary for eligible nationals of Yemen (or individuals having no nationality who last habitually resided in Yemen) to (1) re-register for TPS and to apply for renewal of their EADs with USCIS or (2) submit an initial registration application under the redesignation and apply for an EAD.

Re-registration is limited to individuals who have previously registered for TPS under the designation of Yemen and whose applications have been granted.

For individuals who have already been granted TPS under Yemen's designation, the 60-day re-registration period runs from July 9, 2021 through September 7, 2021. USCIS will issue new EADs with a March 3, 2023 expiration date to eligible Yemeni TPS beneficiaries who timely re-register and apply for EADs. Given the timeframes involved with processing TPS re-registration applications, DHS recognizes that not all re-registrants may receive new EADs before their current EADs expire on September 3, 2021. Accordingly, through this **Federal Register** Notice, DHS automatically extends the validity of EADs previously issued under the TPS designation of Yemen for 180 days, through March 2, 2022. Therefore, TPS beneficiaries can show their EADs with: (1) A September 3, 2021 expiration date on the face of the card and (2) an A–12 or C–19 category code as proof of continued employment authorization through March 2, 2022. This Notice explains how TPS beneficiaries and their employers may determine which EADs are automatically extended and how this affects the Form I–9, Employment Eligibility Verification, E-Verify, and USCIS Systematic Alien Verification for Entitlements (SAVE) processes.

Individuals who have a Yemen TPS application (Form I–821) and/or Application for Employment Authorization (Form I–765) that was still pending as of July 9, 2021 do not need to file either application again. If USCIS approves an individual's Form I–821, USCIS will grant the individual TPS through March 3, 2023. Similarly, if USCIS approves a pending TPS-related Form I–765, USCIS will issue the individual a new EAD that will be valid through the same date. There are approximately 1,700 current beneficiaries under Yemen's TPS designation.[2]

Under the redesignation, individuals who do not have TPS may submit an initial application during the initial registration period that runs from July 9, 2021 and runs through the full length of the redesignation period ending March 3, 2023. In addition to demonstrating continuous residence in the United States since July 5, 2021 and meeting other eligibility criteria, initial applicants for TPS under this redesignation must demonstrate that they have been continuously physically present in the United States since September 4, 2021, the effective date of this redesignation of Yemen, before USCIS may grant them TPS. The DHS Office of Immigration Statistics has estimated that approximately 480 individuals may become newly eligible for TPS under the redesignation of Yemen.

What is temporary protected status (TPS)?

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the INA, or to eligible persons without nationality who last habitually resided in the designated country.
- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to obtain EADs so long as they continue to meet the requirements of TPS.
- TPS beneficiaries may also apply for and be granted travel authorization as a matter of discretion. Upon return from such authorized travel, TPS beneficiaries retain the same immigration status they had prior to the travel.
- To qualify for TPS, beneficiaries must meet the eligibility standards at INA section 244(c)(1)–(2), 8 U.S.C. 1254a(c)(1)–(2).
- When the Secretary terminates a country's TPS designation, beneficiaries return to one of the following:
  - The same immigration status or category that they maintained before TPS, if any (unless that status or category has since expired or been terminated); or
  - Any other lawfully obtained immigration status or category they received while registered for TPS, as long as it is still valid beyond the date TPS terminates.

When was Yemen designated for TPS?

Former Secretary of Homeland Security Jeh Johnson initially designated Yemen for TPS on September 3, 2015, based on ongoing armed conflict in the country resulting from the July 2014 offensive by the Houthis, a northern opposition group that initiated a violent, territorial expansion across the country, eventually forcing Yemeni government leaders into exile in Saudi Arabia. *See Designation of Republic of Yemen for Temporary Protected Status, 80 FR 53319 (Sept. 3, 2015).* On January 4, 2017, former Secretary Johnson announced an 18-month extension of Yemen's existing designation and a redesignation of Yemen for TPS on the dual bases of ongoing armed conflict and extraordinary and temporary conditions. *See Extension and Redesignation of Republic of Yemen for Temporary Protected Status, 82 FR 859 (Jan. 4, 2017).* In July 2018, former Secretary Kirstjen Nielsen extended Yemen's designation for 18 months, though March 3, 2020. *See Extension of the Designation of Yemen for Temporary Protected Status, 83 FR 40307 (Aug. 14, 2018).* Most recently, former Acting Secretary Chad Wolf extended Yemen's TPS designation for an additional 18 months through September 3, 2021. *See Extension of the Designation of Yemen for Temporary Protected Status, 85 FR 12313 (Mar. 2, 2020).*

What authority does the Secretary have to extend the designation of Yemen for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate agencies of the U.S. Government (Government), to designate a foreign state (or part thereof) for TPS if the Secretary determines that certain country conditions exist.[3] The decision to designate any foreign state (or part thereof) is a discretionary decision, and there is no judicial review of any determination with respect to the designation, extension or termination of

[2] Data extracted from the Computer Linked Application Information Management System (CLAIMS3) and the USCIS Electronic Immigration System (ELIS) database in March, 2021.

[3] As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (codifying the Homeland Security Act of 2002, tit. XV, section 1517).

a designation. See INA section 244(b)(5)(A). The Secretary, in his/her discretion, may then grant TPS to eligible nationals of that foreign state (or individuals having no nationality who last habitually resided in the designated country). *See* INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a country's TPS designation or extension, the Secretary, after consultation with appropriate Government agencies, must review the conditions in the foreign state designated for TPS to determine whether the conditions for the TPS designation continue to be met. *See* INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary does not determine that the foreign state no longer meets the conditions for TPS designation, the designation will be extended for an additional period of 6 months or, in the Secretary's discretion, 12 or 18 months. *See* INA section 244(b)(3)(A), (C), 8 U.S.C. 1254a(b)(3)(A), (C). If the Secretary determines that the foreign state no longer meets the conditions for TPS designation, the Secretary must terminate the designation. *See* INA section 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

What is the Secretary's authority to redesignate Yemen for TPS?

In addition to extending an existing TPS designation, the Secretary, after consultation with appropriate Government agencies, may redesignate a country (or part thereof) for TPS.[4] *See* section 244(b)(1) of the Act, 8 U.S.C. 1254a(b)(1); *see also* section 244(c)(1)(A)(i) of the Act, 8 U.S.C. 1254a(c)(1)(A)(i) (requiring that ''the alien has been continuously physically present since the effective date of *the most recent designation of the state*'') (emphasis added).

When the Secretary designates or redesignates a country for TPS, the Secretary also has the discretion to establish the date from which TPS applicants must demonstrate that they have been ''continuously resid[ing]'' in the United States. *See* section 244(c)(1)(A)(ii) of the Act, 8 U.S.C. 1254a(c)(1)(A)(ii). The Secretary has determined that the ''continuous residence'' date for applicants for TPS under the redesignation of Yemen shall be July 5, 2021. Initial applicants for TPS under this redesignation must also show they have been ''continuously physically present'' in the United States since September 4, 2021, which is the effective date of the Secretary's most recent designation, or redesignation, of Yemen. *See* section 244(c)(1)(A)(i) of the Act, 8 U.S.C. 1254a(c)(1)(A)(i). For each initial TPS application filed under the redesignation, the final determination of whether the applicant has met the ''continuous physical presence'' requirement cannot be made until September 4, 2021. USCIS, however, will issue employment authorization documentation, as appropriate, during the registration period in accordance with 8 CFR 244.5(b).

Why is the Secretary extending the TPS designation for Yemen and simultaneously redesignating Yemen for TPS through March 3, 2023?

DHS has reviewed conditions in Yemen. Based on this review and after consulting with DOS, the Secretary has determined that an 18-month extension is warranted because the armed conflict is ongoing, and the extraordinary and temporary conditions that prompted the 2017 redesignation of Yemen persist. The Secretary has further determined that the conditions support redesignating Yemen for TPS under section 244(b)(1)(A) and (C) of the Act and changing the dates for ''continuous residence'' and ''continuous physical presence'' in the United States that applicants must meet, in addition to other requirements, to be eligible for TPS.

In September 2014, the Houthi clan, with their armed wing, Ansar Allah, and forces allied with them, launched an attack on Sana'a, Yemen's capital city, and much of the surrounding areas in an attempt to remove Yemen's President Abdu Rabbu Mansour Hadi.[5] The armed conflict in Yemen escalated on March 25, 2015, when a coalition that included Saudi Arabia and the United Arab Emirates (UAE) entered the conflict with the aim of retaking the Houthis' territorial gains and returning President Hadi to power.[6] Now in its seventh year, the protracted conflict has shown no sign of abating, as fighting between Houthi and government forces continues.[7]

There are 24.1 million people (approximately 80% of the population) in need of humanitarian assistance as a result of civil war and conflict in Yemen.[8] The United Nations High Commissioner for Refugees (UNHCR) has recorded 69,160 Yemeni refugees and asylum-seekers in neighboring countries.[9] Over 4 million people have been internally displaced within Yemen, and 166,000 of those were displaced in 2020.[10] The number of those killed since the escalation in violence in 2015 is estimated at over 233,000 individuals.[11] The protracted armed conflict has resulted in high levels of food insecurity, limited access to water and medical care, and the large-scale destruction of Yemen's infrastructure and cultural heritage.[12]

The ongoing conflict has deepened Yemen's difficult economic and humanitarian situation. The food security situation has significantly deteriorated, with 16.2 million people experiencing food insecurity.[13] The conflict has also severely impacted the delivery of basic services, including health services, water, sanitation, and education. UNICEF estimates that 18 million people in Yemen (approximately 59% of the population) do not currently have access to clean water and sanitation.[14] Infrastructure damage as a result of the conflict has further constrained service delivery and relief efforts, as roads, bridges, flood control systems, health facilities, airports, and schools have been damaged or destroyed in the conflict.[15] Even if a political resolution to the conflict is reached, Yemen will be faced with tremendous reconstruction needs. Additionally, thousands of landmines have been placed during the conflict,

[4] This extension and redesignation of TPS for Yemen is one of several instances in which the Secretary and, prior to the establishment of DHS, the Attorney General have simultaneously extended a country's TPS designation and redesignated the country for TPS. *See, e.g.,* 76 FR 29000 (May 19, 2011) (extension and redesignation for Haiti); 69 FR 60168 (Oct. 7, 2004) (extension and redesignation for Sudan); 62 FR 16608 (Apr. 7, 1997) (extension and redesignation for Liberia).

[5] *The War in Yemen and the Making of a Chaos State,* The Atlantic, February 3, 2018.

[6] *Saudi Arabia bombs Yemen, launches coalition op against Houthi rebels,* Reuters, March 25, 2015.

[7] Kali Robinson, *Yemen's Tragedy: War, Stalemate, and Suffering,* Council on Foreign Relations, Feb. 5, 2021.

[8] The United Nations in Yemen, *https://yemen.un.org/en/about/about-the-un,* (last visited April 26, 2021).

[9] Refugee Data Finder, The UN Refugee Agency, UNHCR, *https://www.unhcr.org/refugee-statistics/download/?url=Gb4fe1* (last visited Apr. 16, 2021).

[10] *Operational Update: Yemen,* UNHCR, April 15, 2021.

[11] *UN humanitarian office puts Yemen war dead at 233,000, mostly from 'indirect causes',* UN News, Dec. 1, 2020.

[12] *Heritage at Risk in Yemen,* UNESCO, *https://en.unesco.org/galleries/heritage-risk-yemen* (last visited April 16, 2021).

[13] *WFP Yemen Emergency Dashboard,* World Food Programme, March 2021.

[14] UNICEF Yemen, *Water, Sanitation, Hygiene, https://www.unicef.org/yemen/water-sanitation-and-hygiene* (last visited April 23, 2021).

[15] *Saudi-led attacks devastated Yemen's civilian infrastructure, dramatically worsening the humanitarian crisis,* The Washington Post, Feb. 22, 2021.

with mine clearance likely taking years to complete.[16]

COVID–19 has devastated what remained of Yemen's healthcare infrastructure after years of protracted conflict. In April of 2021, it was reported that a new wave of COVID infections had more than doubled the number of confirmed cases in the preceding six weeks, and that while health facilities are increasingly turning people away for lack of space and supplies, reporting mechanisms capture only a small share of cases.[17] In December of 2020, it was reported that only 51% of Yemen's health facilities were functioning, and the country had desperately low testing capacity for COVID–19, a total of only 700 intensive care beds, and just 500 ventilators available for a population of over 30 million people.[18] In July of 2020, approximately 20% of the country's 333 districts had no medical doctors, with numbers continuing to decline as scores of doctors died from the virus.[19] Healthcare for mothers and their babies is on the brink of collapse, with only 20% of the remaining healthcare facilities providing maternal and newborn healthcare as of December 2020.[20] One woman and six newborns in Yemen die every two hours due to complications during pregnancy or childbirth.[21]

Yemen's citizens have also been beleaguered by a cholera outbreak since 2016.[22] Between October 2016 and December 2020, 2,510,806 cases of cholera were recorded in Yemen.[23] COVID–19 can exacerbate death tolls in areas with cholera outbreaks, because the twin crises can overwhelm the healthcare system, and COVID–19 outbreaks can discourage cholera patients from seeking medical attention.[24] The cholera outbreak in Yemen is considered to be the worst in modern times, affecting all other major health crises, including COVID–19, and contributing to widespread malnutrition.[25]

Since March of 2020, the economy of Yemen has contracted sharply from an already low base.[26] The COVID–19 pandemic depressed the worldwide oil market, which was particularly problematic for Yemen as the oil sector was previously the only large export earner in the Yemeni economy.[27] Yemen's private sector has suffered greatly from the armed conflict, and the shrinking of the economy has also affected the ability of laborers to bring home wages due to an extremely unreliable supply chain and a coercive business environment.[28]

Based upon this review and after consultation with appropriate Government agencies, the Secretary has determined that:

- The conditions supporting Yemen's designation for TPS continue to be met. *See* INA section 244(b)(3)(A) and (C), 8 U.S.C. 1254a(b)(3)(A) and (C).
- There continues to be an ongoing armed conflict in Yemen and, due to such conflict, requiring the return to Yemen of Yemeni nationals (or individuals having no nationality who last habitually resided in Yemen) would pose a serious threat to their personal safety. *See* INA section 244(b)(1)(A), 8 U.S.C. 1254a(b)(1)(A).
- There continue to be extraordinary and temporary conditions in Yemen that prevent Yemeni nationals (or individuals having no nationality who last habitually resided in Yemen) from returning to Yemen in safety, and it is not contrary to the national interest of the United States to permit Yemeni TPS beneficiaries to remain in the United States temporarily. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).
- The designation of Yemen for TPS should be extended for an 18-month period, from September 4, 2021, through March 3, 2023. *See* INA section 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C).
- Yemen should be simultaneously redesignated for TPS effective September 4, 2021, through March 3, 2023, on the statutory bases of ongoing armed conflict and extraordinary and temporary conditions. *See* section 244(b)(1)(A) and (C) and (b)(2) of the Act, 8 U.S.C. 1254a(b)(1)(A) and (C) and (b)(2).
- Under the redesignation, the Secretary has determined that TPS applicants must demonstrate that they have continuously resided in the United States since July 5, 2021.
- Initial TPS applicants under the redesignation must demonstrate that they have been continuously physically present in the United States since September 4, 2021, the effective date of the redesignation of Yemen for TPS.
- There are approximately 1,700 current Yemen TPS beneficiaries who are expected to be eligible to re-register for TPS under the extension.[29]
- It is estimated that approximately 480 additional individuals may be eligible for TPS under the redesignation of Yemen. This estimate includes Yemenis in the United States as nonimmigrants or without immigration status.

Notice of Extension of the TPS Designation and Redesignation of Yemen for TPS

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, I have determined, after consultation with the appropriate Government agencies, the conditions supporting Yemen's designation for TPS continue to be met. *See* INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). On the basis of this determination, I am simultaneously extending the existing designation of TPS for Yemen for 18 months, from September 4, 2021 through March 3, 2023 and redesignating Yemen for TPS for the same 18-month period. *See* INA section 244(b)(1)(A), (b)(1)(C) and (b)(2); 8 U.S.C. 1254a(b)(1)(A), (b)(1)(C), and (b)(2).

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

Required Application Forms and Application Fees to Register or Re-register for TPS

To register or re-register for TPS based on the designation of Yemen, you *must* submit an Application for Temporary Protected Status (Form I–821). If you are filing an initial application, you must pay the fee for the Application for Temporary Protected Status (Form I–821) or, if you can demonstrate an inability to pay the fee, you may be able

[16] *Yemen: Houthi Landmines Kill Civilians, Block Aid,* Human Rights Watch, April 22, 2019.

[17] Under-Secretary-General for Humanitarian Affairs and Emergency Relief Coordinator, Mark Lowcock: Briefing to the Security Council on the Humanitarian Situation in Yemen, United Nations Office for the Coordination of Humanitarian Affairs, April 15, 2021.

[18] *A crisis with no end in sight: How the ongoing crisis in Taiz Governorate continues to put civilians at risk,* Oxfam, p. 3, Dec. 2020.

[19] *Agencies fear hidden cholera deaths in Yemen as Covid-19 overwhelms clinics,* The Guardian, July 28, 2020.

[20] *After years of conflict, Yemen remains the world's worst humanitarian crisis, a UNFPA 2021 appeal shows,* Reliefweb, Dec. 7, 2020.

[21] *After years of conflict, Yemen remains the world's worst humanitarian crisis, a UNFPA 2021 appeal shows,* Reliefweb, Dec. 7, 2020.

[22] *Yemen's cholera outbreak now the worst in history as millionth case looms,* The Guardian, Oct. 12, 2017.

[23] *Cholera Situation in Yemen, December 2020,* World Health Organization, Dec. 2020.

[24] Osama B. Hassan & Laura B. Nellums, *Cholera during COVID–19: The forgotten threat for forcibly displaced populations,* EClinicalMedicine published by The Lancet, Volume 32, Feb. 11, 2021.

[25] *Agencies fear hidden cholera deaths in Yemen as Covid-19 overwhelms clinics,* The Guardian, July 28, 2020.

[26] *Republic of Yemen,* World Bank Economic Update, April 2021.

[27] *Republic of Yemen,* World Bank Economic Update, April 2021.

[28] *Republic of Yemen,* World Bank Economic Update, April 2021.

[29] *See* FN 2.

to have the fee waived. A fee waiver may be requested by submitting a Request for a Fee Waiver (Form I–912). If you are filing an application for re-registration, you do not need to pay the fee for the Application for Temporary Protected Status (Form I–821). There is no Form I–821 fee for re-registration. See 8 CFR 244.17. You may be required to pay the biometric services fee. If you can demonstrate an inability to pay the biometric services fee, you may request to have the fee waived. Please see additional information under the ''Biometric Services Fee'' section of this Notice.

EAD information if you are already a TPS Yemen Beneficiary:

Through this **Federal Register** Notice, your existing EAD issued under the TPS designation of Yemen with the expiration date of September 3, 2021, is automatically extended for 180 days, through March 2, 2022. Although not required to do so, if you want to obtain a new EAD valid through March 3, 2023, you must file an Application for Employment Authorization (Form I–765) and pay the Form I–765 fee (or request a fee waiver). If you do not want a new EAD, you do not have to file Form I–765 and pay the Form I–765 fee. If you do not want to request a new EAD now, you may also file Form I–765 at a later date and pay the fee (or request a fee waiver), provided that you still have TPS or a pending TPS application. You may file the application for a new EAD either prior to or after your current EAD has expired. However, you are strongly encouraged to file your application for a new EAD as early as possible to avoid gaps in the validity of your employment authorization documentation and to ensure that you receive your new EAD by March 2, 2022.

If you have a Form I–821 and/or Form I–765 that was still pending as of July 9, 2021, then you do not need to file either application again. If USCIS approves your pending TPS application, USCIS will grant you TPS through March 3, 2023. Similarly, if USCIS approves your pending TPS-related Form I–765, it will be valid through the same date.

EAD information if you are not already a TPS Yemen Beneficiary:

Everyone must provide their employer with documentation showing that they have the legal right to work in the United States. You do not need to have an EAD, but you can obtain one and it will prove your legal right to work. If you are applying for initial registration and want an EAD, you must file and pay the fee for the Application for Employment Authorization (Form I–765). If you do not want to request an EAD now, you may also file Form I–765 at a later date and pay the fee (or request a fee waiver), provided that you still have TPS or a pending TPS application.

For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at *http://www.uscis.gov/tps.* Fees for the Form I–821, the Form I–765, and biometric services are also described in 8 CFR 103.7(b)(1)(i).

Biometric Services Fee

Biometrics (such as fingerprints) are required for all applicants 14 years of age and older. Those applicants must generally submit a biometric services fee. As previously stated, if you can demonstrate an inability to pay the biometric services fee, you may be able to have the fee waived. A fee waiver may be requested by submitting a Request for Fee Waiver (Form I–912). For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at *www.uscis.gov/tps.* If necessary, you may be required to visit an Application Support Center to have your biometrics captured. For additional information on the USCIS biometrics screening process, please see the USCIS Customer Profile Management Service Privacy Impact Assessment, available at *www.dhs.gov/privacy.*

Refiling a TPS Initial Registration Application After Receiving Notice That the Fee Waiver Request Was Not Granted

You should file as soon as possible so USCIS can process your application and issue any EAD promptly, if you requested one. If you receive a denial of a fee waiver request related to your initial TPS application, you must refile your Form I–821 for TPS along with the required fees no later than March 3, 2023, in order to continue seeking initial TPS. If your fee waiver request was not granted, you may also refile your Form I–765, with fee, either with your Form I–821 or at a later time, if you choose.

Note: An initial applicant for TPS must pay the Form I–821 filing fee and those applicants age 14 or older must also pay the biometric services fee, unless granted a fee waiver. However, you may decide to wait to request an EAD. Therefore, you do not have to file the Form I–765 or pay the associated Form I–765 fee (or request a fee waiver) at the time of registration, and could wait to seek an EAD until after USCIS has approved your TPS registration application or at any later date you decide you want to request an EAD. If you choose to do this, to register for TPS you only need to file the Form I–821 with the $50 filing fee and the biometric services fee, if applicable (or request a fee waiver).

Refiling a TPS Re-Registration Application After Receiving Notice That the Fee Waiver Request Was Not Granted

You should file as soon as possible so USCIS can process your application and issue any EAD promptly, if you requested one. Properly filing early will also allow you to have time to refile your application before the deadline, should USCIS not grant your fee waiver request. If you receive a notice that your fee waiver request was not granted and are unable to refile by September 7, 2021, you may still refile your Form I–821 with the biometrics fee. USCIS will review this situation to determine whether you established good cause for late TPS re-registration. However, you are urged to refile within 45 days of the date on any USCIS notice that the fee waiver was not granted, if possible. *See* INA section 244(c)(3)(C); 8 U.S.C. 1254a(c)(3)(C); 8 CFR 244.17(b). For more information on good cause for late re-registration, visit the USCIS TPS web page at *http://www.uscis.gov/tps.* If your fee waiver request is not granted, you may also refile your Form I–765 with fee either with your Form I–821 or at a later time, if you choose.

Note: A re-registering TPS beneficiary age 14 and older must pay the biometric services fee (but not the Form I–821 filing fee), or request a fee waiver, when filing a TPS re-registration application. However, you may decide to wait to request an EAD. Therefore, you do not have to file the Form I–765 or pay the associated Form I–765 fee (or request a fee waiver) at the time of re-registration, and could wait to seek an EAD until after USCIS has approved your TPS re-registration application or at any later date you decide you want to request an EAD. If you choose to do this, to re-register for TPS you would only need to file the Form I–821 with the biometric services fee, if applicable (or request a fee waiver).

Mailing Information

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If you would like to send your application by:	Then, mail your application to:
U.S. Postal Service	U.S. Citizenship and Immigration Services, Attn: TPS Yemen, P.O. Box 6943, Chicago, IL 60680–6943.
FedEx, UPS, or DHL	U.S. Citizenship and Immigration Services, Attn: TPS Yemen (Box 6943), 131 S. Dearborn Street—3rd Floor, Chicago, IL 60603–5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA) and you wish to request an EAD or are re-registering for the first time following a grant of TPS by an IJ or the BIA, please mail your application to the appropriate mailing address in Table 1. When re-registering and requesting an EAD based on an IJ/BIA grant of TPS, please include a copy of the IJ or BIA order granting you TPS with your application. This will help us to verify your grant of TPS and process your application.

Supporting Documents

The filing instructions on the Form I–821 list all the documents needed to establish eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying or registering for TPS on the USCIS website at *www.uscis.gov/tps* under ''Yemen.''

Employment Authorization Document (EAD)

How can I obtain information on the status of my TPS application and EAD request?

To get case status information about your TPS application, including the status of an EAD request, you can check Case Status Online at *http://www.uscis.gov,* or visit the USCIS Contact Center at *uscis.gov/contactcenter.* If your Form I–765 has been pending for more than 90 days, and you still need assistance, you may ask a question about your case online at *egov.uscis.gov/e-request/Intro.do* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

Am I eligible to receive an automatic 180-day extension of my current EAD through March 2, 2022, using this ***Federal Register*** *Notice?*

Yes. Regardless of your country of birth, provided that you currently have a Yemen TPS-based EAD with an expiration date of September 3, 2021, on the face of the card, bearing the notation A–12 or C–19 under Category, this notice automatically extends your EAD through March 2, 2022. Although this **Federal Register** Notice automatically extends your EAD through March 2, 2022, you must re-register timely for TPS in accordance with the procedures described in this **Federal Register** Notice to maintain your TPS and employment authorization.

When hired, what documentation may I show to my employer as evidence of employment authorization and identity when completing Form I–9?

You can find the Lists of Acceptable Documents on the third page of Form I–9 as well as the Acceptable Documents web page at *https://www.uscis.gov/i-9-central/acceptable-documents.* Employers must complete Form I–9 to verify the identity and employment authorization of all new employees. Within three days of hire, employees must present acceptable documents to their employers as evidence of identity and employment authorization to satisfy Form I–9 requirements.

You may present any document from List A (which provides evidence of both identity and employment authorization), or one document from List B (which provides evidence of your identity) together with one document from List C (which provides evidence of employment authorization), or you may present an acceptable receipt for List A, List B, or List C documents as described in the Form I–9 instructions. Employers may not reject a document based on a future expiration date. You can find additional information about Form I–9 on the I–9 Central web page at *http://www.uscis.gov/I-9Central.*

An EAD is an acceptable document under List A. See the section ''How do my employer and I complete Form I–9 using my automatically extended EAD for a new job?'' of this **Federal Register** Notice for further information. If your EAD has an expiration date of September 3, 2021 and states A–12 or C–19 under Category, it has been extended automatically by virtue of this **Federal Register** Notice and you may choose to present your EAD to your employer as proof of identity and employment eligibility for Form I–9 through March 2, 2022, unless your TPS has been withdrawn or your request for TPS has been denied.

What documentation may I present to my employer for Form I–9 if I am already employed but my current TPS-related EAD is set to expire?

Even though your EAD has been automatically extended, your employer is required by law to ask you about your continued employment authorization. Your employer may need to re-inspect your automatically extended EAD to check the Card Expires date and Category code if your employer did not keep a copy of your EAD when you initially presented it. Once your employer has reviewed the Card Expiration date and Category code, your employer should update the EAD expiration date in Section 2 of Form I–9. See the section ''What updates should my current employer make to Form I–9 if my EAD has been automatically extended?'' of this **Federal Register** Notice for further information. You may show this **Federal Register** Notice to your employer to explain what to do for Form I–9 and to show that your EAD has been automatically extended through March 2, 2022, but you are not required to do so. The last day of the automatic EAD extension is March 2, 2022. Before you start work on March 3, 2022, your employer is required by law to reverify your employment authorization in Section 3 of Form I–9. By that time, you must present any document from List A or any document from List C on Form I–9 Lists of Acceptable Documents, or an acceptable List A or List C receipt described in the Form I–9 instructions to reverify employment authorization.

Your employer may not specify which List A or List C document you must present and cannot reject an acceptable receipt.

Can my employer require that I provide any other documentation to prove my status, such as proof of my Yemeni citizenship or a Form I–797C showing I re-registered for TPS?

No. When completing Form I–9, including reverifying employment authorization, employers must accept any documentation that appears on the Form I–9 Lists of Acceptable Documents that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt.

Employers need not reverify List B identity documents. Therefore, employers may not request proof of Yemeni citizenship or proof of re-registration for TPS when completing Form I–9 for new hires or reverifying the employment authorization of current employees. If you present an EAD that has been automatically extended, employers should accept it as a valid List A document so long as the EAD reasonably appears to be genuine and relates to you. Refer to the Note to Employees section of this **Federal Register** Notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

How do my employer and I complete Form I–9 using my automatically extended EAD for a new job?

When using an automatically extended EAD to complete Form I–9 for a new job before March 3, 2022, for Section 1, you should:

a. Check ''An alien authorized to work until'' and enter March 2, 2022 as the ''expiration date''; and

b. Enter your Alien Number/USCIS number or A-Number where indicated (your EAD or other document from DHS will have your USCIS number or A-Number printed on it; the USCIS number is the same as your A-Number without the A prefix).

2. For Section 2, employers should:

a. Determine if the EAD is auto-extended by ensuring it is in category A–12 or C–19 and has a Card Expires date of September 3, 2021;

b. Write in the document title;

c. Enter the issuing authority;

d. Provide the document number; and

e. Write March 2, 2022, as the expiration date.

Before the start of work on March 3, 2022, employers must reverify the employee's employment authorization in Section 3 of Form I–9.

What updates should my current employer make to Form I–9 if my EAD has been automatically extended?

If you presented a TPS-related EAD that was valid when you first started your job and your EAD has now been automatically extended, your employer may need to re-inspect your current EAD if they do not have a copy of the EAD on file. Your employer should determine if your EAD is automatically extended by ensuring that it contains Category A–12 or C–19 and has a Card Expires date of September 3, 2021, on the front of the card.

If your employer determines that your EAD has been automatically extended, your employer should update Section 2 of your previously completed Form I–9 as follows:

1. Write EAD EXT and March 2, 2022, as the last day of the automatic extension in the Additional Information field; and

2. Initial and date the correction.

Note: This is not considered a reverification. Employers do not complete Section 3 until either the 180-day automatic extension has ended, or the employee presents a new document to show continued employment authorization, whichever is sooner. By March 3, 2022, when the employee's automatically extended EAD has expired, employers are required by law to reverify the employee's employment authorization in Section 3.

If I am an employer enrolled in E-Verify, how do I verify a new employee whose EAD has been automatically extended?

Employers may create a case in E-Verify for a new employee by entering the number from the Document Number field on Form I–9 into the document number field in E-Verify. Employers should enter March 2, 2022, as the expiration date for an EAD that has been extended under this **Federal Register** Notice.

If I am an employer enrolled in E-Verify, what do I do when I receive a ''Work Authorization Documents Expiring'' alert for an automatically extended EAD?

E-Verify automated the verification process for TPS-related EADs that are automatically extended. If you have employees who provided a TPS-related EAD when they first started working for you, you will receive a ''Work Authorization Documents Expiring'' case alert when the auto-extension period for this EAD is about to expire. Before this employee starts work on March 3, 2022, you must reverify his or her employment authorization in Section 3 of Form I–9. Employers may not use E-Verify for reverification.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This **Federal Register** Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I9Central@uscis.dhs.gov.* USCIS accepts calls and emails in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process (Form I–9 and E-Verify), employers may call the U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section (IER) Employer Hotline at 800–255–8155 (TTY 800–237–2515). IER offers language interpretation in numerous languages. Employers may also email IER at *IER@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email USCIS at *I-9Central@uscis.dhs.gov.* Calls are accepted in English, Spanish, and many other languages. Employees or applicants may also call the IER Worker Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship, immigration status, or national origin, including discrimination related to Form I–9 and E-Verify. The IER Worker Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt as described in the Form I–9 Instructions. Employers may not require extra or additional documentation beyond what is required for Form I–9 completion. Further, employers participating in E-Verify who receive an E-Verify case result of Tentative Nonconfirmation (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from an employee's Form I–9 differs from Federal or state government records.

Employers may not terminate, suspend, delay training, withhold or lower pay, or take any adverse action against an employee because of the TNC while the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized

employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). For more information about E-Verify-related discrimination or to report an employer for discrimination in the E-Verify process based on citizenship, immigration status, or national origin, contact IER's Worker Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Form I–9 and E-Verify procedures is available on the IER website at *https://www.justice.gov/ier* and on the USCIS and E-Verify websites at *https://www.uscis.gov/i-9-central* and *https://www.e-verify.gov.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

For Federal purposes, TPS beneficiaries presenting an automatically extended EAD as referenced in this **Federal Register** Notice do not need to show any other document, such as an I–797C Notice of Action or this **Federal Register** Notice, to prove that they qualify for this extension. However, while Federal Government agencies must follow the guidelines laid out by the Federal Government, state and local government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, state, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary, show you are authorized to work based on TPS or other status, and/or that may be used by DHS to determine whether you have TPS or other immigration status. Examples of such documents are:

- Your current EAD with a TPS category code of A12 or C19;
- Your Form I–94, Arrival/Departure Record;
- Your Form I–797, Notice of Action, reflecting approval of your Form I–765; or
- Your Form I–797, the notice of approval, for a past or current Form I–821, if you received one from USCIS.

Check with the government agency regarding which document(s) the agency will accept. Some benefit-granting agencies use USCIS' Systematic Alien Verification for Entitlements (SAVE) program to confirm the current immigration status of applicants for public benefits. While SAVE can verify when an individual has TPS, each agency's procedures govern whether they will accept an unexpired EAD, Form I–797, or Form I–94, Arrival/Departure Record. If an agency accepts the type of TPS-related document you are presenting, such as an EAD, the agency should accept your automatically extended EAD. It may assist the agency if you:

a. Present the agency with a copy of the relevant **Federal Register** Notice showing the extension of TPS-related documentation in addition to your recent TPS-related document with your A-number, USCIS number or Form I–94 number;

b. Explain that SAVE will be able to verify the continuation of your TPS using this information; and

c. Ask the agency to initiate a SAVE query with your information and follow through with additional verification steps, if necessary, to get a final SAVE response verifying your TPS.

You can also ask the agency to look for SAVE notices or contact SAVE if they have any questions about your immigration status or automatic extension of TPS-related documentation. In most cases, SAVE provides an automated electronic response to benefit-granting agencies within seconds, but, occasionally, verification can be delayed. You can check the status of your SAVE verification by using CaseCheck at *save.uscis.gov/casecheck/.* CaseCheck is a free service that lets you follow the progress of your SAVE verification case using your date of birth and one immigration identifier number (A-number, USCIS number or Form I–94 number) or Verification Case Number. If an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the SAVE response is correct, find detailed information on how to make corrections or update your immigration record, make an appointment, or submit a written request to correct records. More information can be found on the SAVE website at *www.uscis.gov/*save.

[FR Doc. 2021–14670 Filed 7–7–21; 4:15 pm]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NCR–WHHO–NPS0032047; PPNCWHHOP0, PPMVSIE1Z.I00000 (212); OMB Control Number 1024–0277]

Agency Information Collection Activities; National Park Service President's Park National Christmas Tree Music Program Application

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 7, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email at *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–0277 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Katie Wilmes, Chief of Interpretation, President's Park by email at *Katie_Wilmes@nps.gov,* or by telephone at 202–208–1631. Please reference OMB Control Number 1024–0277 in the subject line of your comments. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies 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 especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you 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.

Abstract: Authorized by the NPS Organic Act of 1916, 54 U.S.C. 100101 *et seq.,* the NPS has broad authority to regulate the use of the park areas under its jurisdiction. Consistent with the Organic Act, as well as the Constitution's Establishment Clause which mandates government neutrality and allows the placement of holiday secular and religious displays, the National Christmas Tree Music Program's holiday musical entertainment may include both holiday secular and religious music. To ensure that any proposed music selection is consistent with the Establishment Clause, and presented in a prudent and objective manner as a traditional part of the culture and heritage of this annual holiday event, it must be approved in advance by the NPS.

The NPS National Christmas Tree Music Program at President's Park is intended to provide musical entertainment for park visitors during December on the Ellipse, where in celebration of the holiday season, visitors can observe the National Christmas Tree, visit assorted yuletide displays, and attend musical presentations. Each year, park officials accept applications from musical groups who wish to participate in the annual National Christmas Tree Program. The NPS uses Form 10–942, ''National Christmas Tree Music Program Application'' to accept applications from the public for participation in the program. The form collects the following information:

- Contact name, phone number, and email
- Group name and location (city, state)
- Preferred performance dates and times
- Music selections/song list
- Equipment needs
- Number of performers
- Type of group (choir, etc.)
- Acknowledgement of the musical entertainment policy

Park officials use the information collected to select, plan, schedule, and contact performers for the National Christmas Tree Program.

Title of Collection: National Park Service President's Park National Christmas Tree Music Program Application.

OMB Control Number: 1024–0277.

Form Number: NPS Form 10–942, ''National Christmas Tree Music Program Application.''

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Local, national, and international bands, choirs, or dance groups.

Total Estimated Number of Annual Respondents: 75.

Total Estimated Number of Annual Responses: 75.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 19.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

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.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2021–14645 Filed 7–8–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1270]

Institution of Investigation; Certain Casual Footwear and Packaging Thereof

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 8, 2010, under section 337 of the Tariff Act of 1930, as amended, on behalf of Crocs, Inc. of Broomfield, Colorado. Supplements to the complaint were filed on June 10, June 17, June 23, and June 28, 2021. The complaint, as corrected and supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain casual footwear and packaging thereof by reason of infringement of one or more of U.S. Trademark Registration No. 3,836,415 (''the '415 mark''); U.S. Trademark Registration No. 5,149,328 (''the '328 mark''); and U.S. Trademark Registration No. 5,273,875 (''the '875 mark'') (collectively, ''Asserted Trademarks''), and that an industry in the United States exists as required by the applicable Federal Statute. The complaint, as corrected and supplemented, further alleges violations of section 337 based upon the importation into the United States, or in the sale of certain casual footwear and packaging thereof, by reason of false designation of source or trademark dilution, the threat or effect of which is to destroy or substantially injure an industry in the United States. The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–

2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 6, 2021, *ordered that* —

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:

(a) Whether there is a violation of subsection (a)(1)(C) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of the Asserted Trademarks, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(b) whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, or in the sale of certain products identified in paragraph (2), by reason of false designation of source or trademark dilution, the threat or effect of which is to destroy or substantially injure an industry in the United States;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''casual footwear with holes in the upper and such footwear's packaging'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Crocs, Inc., 13601 Via Varra, Broomfield, Colorado 80020.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Cape Robbin Inc., 1943 West Mission Blvd., Bldg. F, Pomona, CA 91766
Bijora, Inc., d/b/a Akira, 200 N Fairfield Ave., Chicago, IL 60612
Dr. Leonard's Healthcare Corp. d/b/a Carol Wright, 100 Nixon Ln., Edison, NJ 08837
Crocsky, 1401 Lavaca St., Austin, TX 78701
Fullbeauty Brands Inc. d/b/a Kingsize, 1 New York Plaza, New York, NY 10004
Hawkins Footwear, Sports, Military & Dixie Store, 6083 New Jesup Hwy., Suite J, Brunswick, GA 31523
Hobibear Shoes and Clothing Ltd., 173 N 17th Ct., Brighton, CO 80601
Hobby Lobby Stores, Inc., 707 SW 44th St., Oklahoma City, OK 73179
Ink Tee, 811 Wilshire Blvd., Los Angeles, CA 90017
La Modish Boutique, 1773 W San Bernardino Rd., Suite B25, West Covina, CA 91790
Legend Footwear, Inc., d/b/a Wild Diva, 19445 E Walnut Drive North, City of Industry, CA 91789
Loeffler Randall Inc., 588 Broadway, Ste. 1203, New York, NY 10012
Maxhouse Rise Ltd., Flat A, 25/F, United Centre, 95 Queensway, Hong Kong
PW Shoes, Inc. a/k/a P&W, 5830 Grand Ave., 3a, Maspeth, NY 11378
SG Footwear Meser Grp. Inc. a/k/a S. Goldberg & Co., 3 University Plz #400, Hackensack, NJ 07601
Shoe-Nami, Inc., 91 Westbank Expressway, Gretna, LA 70053
Skechers USA, Inc., 228 Manhattan Beach Blvd., Manhattan Beach, CA 90266
Star Bay Group Inc., 390–400 Railroad Ave., Hackensack, NJ 07601
Yoki Fashion International LLC, 1410 Broadway, Suite 1005, New York, NY 10018
Quanzhou ZhengDe Network Corp., d/b/a Amoji, Rm. C–409, No. 2 YanZhi Gallery, Licheng District, Quanzhou, Fujian Province, China 362002
718 Closeouts, 1181 Liberty Ave., Brooklyn, NY 11208
Royal Deluxe Accessories, LLC, 165 Spring St., New Providence, NJ 07974
Fujian Huayuan Well Import and Export Trade Co., Ltd., Rm. 02, Connector of Hongyuan Building 1 and 2, No. 246 Hualin Road, Huada Residential District, Gulou District, Fuzhou, Fujian Province, China 350001

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: July 6, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–14653 Filed 7–8–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–648 and 731–TA–1521–1522 (Final)]

Walk-Behind Lawn Mowers From China and Vietnam

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of walk-behind lawn mowers from China found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

government of China, and threatened with material injury by reason of imports of walk-behind lawn mowers from Vietnam found by Commerce to be sold at LTFV, provided for in subheading 8433.11.00 of the Harmonized Tariff Schedule of the United States.

Background

The Commission instituted these investigations effective May 26, 2020, following receipt of petitions filed with the Commission and Commerce by MTD Products, Inc., Valley City, Ohio. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of walk-behind lawn mowers from China were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and that imports of walk-behind lawn mowers from China and Vietnam were sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on January 29, 2021 (86 FR 7565). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its hearing through video conference on May 18, 2021. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on July 6, 2021. The views of the Commission are contained in USITC Publication 5209 (July 2021), entitled *Walk-Behind Lawn Mowers from China and Vietnam: Investigation Nos. 701–TA–648 and 731–TA–1521–1522 (Final).*

By order of the Commission.
Issued: July 6, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–14649 Filed 7–8–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1545 (Final)]

Utility Scale Wind Towers From Spain; Scheduling of the Final Phase of Anti-Dumping Duty Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: June 25, 2021.

FOR FURTHER INFORMATION CONTACT: Julie Duffy ((202) 708–2579), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: Effective March 19, 2021, the Commission established a general schedule for the conduct of the final phase of its investigations on utility scale wind towers (''wind towers'') from India, Malaysia, and Spain (86 FR 20197, April 16, 2021), following preliminary determinations by the U.S. Department of Commerce (''Commerce'') that imports of subject wind towers from India and Malaysia were subsidized by the governments of India and Malaysia (86 FR 15887, March 25, 2021; and 86 FR 15897, March 25, 2021) and imports of subject wind towers from Spain were being sold in the United States at less than fair value (86 FR 17354, April 2, 2021). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on April 16, 2021 (86 FR 20197). Counsel for the Wind Tower Trade Coalition withdrew its previously filed request to appear at the hearing, after no other parties submitted a request to appear, and indicated a willingness to submit written responses to any Commission questions in lieu of an actual hearing. Consequently, since no party to the investigation requested a hearing, the Commission canceled its hearing in connection with these investigations (86 FR 31730). Parties to these investigations responded to written questions posed by the Commission in their posthearing briefs.

Commerce has issued a final affirmative countervailing duty determination with respect to wind towers from Malaysia (86 FR 30593, June 9, 2021). The Commission is scheduled to issue its final determination as to whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of wind towers from Malaysia provided for in subheadings 7308.20.00 and 8502.31.00 of the Harmonized Tariff Schedule of the United States (''HTSUS'') that have been found by Commerce to be subsidized by the government of Malaysia by July 26, 2021.

Commerce recently has issued a final affirmative antidumping duty determination with respect to wind towers from Spain (86 FR 33656, June 25, 2021). Accordingly, the Commission currently is issuing a supplemental schedule for its antidumping duty investigation on imports of wind towers from Spain.

This supplemental schedule is as follows: The deadline for filing supplemental party comments on Commerce's final antidumping duty determination is July 7, 2021. Supplemental party comments may address only Commerce's final antidumping duty determination regarding imports of wind towers from Spain. These supplemental final comments may not contain new factual information and may not exceed five (5) pages in length. The supplemental staff report in the final phase of this investigation regarding subject imports from Spain will be placed in the nonpublic record on July 19, 2021, and a public version will be issued thereafter.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless

the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.
Issued: July 6, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–14648 Filed 7–8–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2021–0004]

Advisory Committee on Construction Safety and Health (ACCSH): Notice of Meetings

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of ACCSH meeting.

SUMMARY: The Advisory Committee on Construction Safety and Health (ACCSH) will meet August 11, 2021.

DATES: ACCSH will meet from 1:00 p.m. to 5:00 p.m., ET, Wednesday, August 11, 2021.

Submission of comments and requests to speak: Submit comments and requests to speak at the ACCSH meeting by Tuesday, July 27, 2021, identified by the docket number for this **Federal Register** notice (Docket No. OSHA–2021–0004), using the following method:

Electronically: Comments and requests to speak, including attachments, must be submitted electronically at: *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Requests for special accommodations: Please submit requests for special accommodations for this ACCSH meeting by Tuesday, July 27, 2021, to Ms. Gretta Jameson, OSHA, Directorate of Construction, U.S. Department of Labor; telephone: (202) 693–2020; email: *jameson.grettah@dol.gov.*

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general information about ACCSH: Mr. Damon Bonneau, OSHA, Directorate of Construction, U.S. Department of Labor; telephone (202) 693–2183; email: *bonneau.damon@dol.gov.*

Telecommunication requirements: For additional information about the telecommunication requirements for the meeting, please contact Ms. Gretta Jameson, OSHA, Directorate of Construction, U.S. Department of Labor; telephone: (202) 693–2020; email: *jameson.grettah@dol.gov.*

For copies of this ***Federal Register*** *Notice:* Electronic copies of this **Federal Register** Notice are available at: *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available at OSHA's web page at *www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

ACCSH advises the Secretary of Labor and the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) in the formulation of standards affecting the construction industry, and on policy matters arising in the administration of the safety and health provisions under the Contract Work Hours and Safety Standards Act (Construction Safety Act (CSA)) (40 U.S.C. 3701 *et seq.*) and the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) (see also 29 CFR 1911.10 and 1912.3). In addition, the CSA and OSHA regulations require the Assistant Secretary to consult with ACCSH before the agency proposes any occupational safety and health standard affecting construction activities (40 U.S.C. 3704; 29 CFR 1911.10).

ACCSH operates in accordance with the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App. 2), and its implementing regulations (41 CFR 102–3 *et seq.*); and Department of Labor Manual Series Chapter 1–900 (8/31/2020). ACCSH generally meets two to four times a year.

II. Meeting Information

Attendance at this ACCSH meeting will be virtual only. Meeting information will be posted in the Docket (Docket No. OSHA–2021–0004) and on the ACCSH web page, *https://www.osha.gov/advisorycommittee/accsh,* prior to the meeting.

Meeting agenda: The tentative agenda for this meeting includes:

- Acting Assistant Secretary's agency update and remarks;
- Directorate of Construction industry update;
- Discussion of the OSHA Construction Focus Four Hazards;
- ACCSH Workgroup discussion; and,
- Public comment period.

Requests to speak and speaker presentations: Attendees who wish to address ACCSH must submit a request to speak, as well as any written or electronic presentation, by Tuesday, July 27, 2021, using the method listed in the **ADDRESSES** section of this notice. The request must state:

- The amount of time requested to speak;
- The interest you represent (*e.g.,* business, organization, affiliation), if any; and
- A brief outline of your presentation.

PowerPoint presentations and other electronic materials must be compatible with PowerPoint 2010 and other Microsoft Office 2010 formats.

Alternately, you may request to address ACCSH briefly during the public-comment period. At her discretion, the ACCSH Chair may grant requests to address ACCSH as time and circumstances permit.

Docket: OSHA will place comments, requests to speak, and speaker presentations, including any personal information you provide, in the public docket without change, and those documents may be available online at: *http://www.regulations.gov.* Therefore, OSHA cautions interested parties about submitting personal information such as Social Security Numbers and birthdates. OSHA also places in the public docket the meeting transcript, meeting minutes, documents presented at the meeting, and other documents pertaining to the ACCSH meeting. These documents are available online at: *http://www.regulations.gov.* To read or download documents in the public docket for this ACCSH meeting, go to Docket No. OSHA–2021–0004 at: *http://www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *http://www.regulations.gov.* All

submissions are available for inspection and copying, when permitted, at the OSHA Docket Office. For information on using *http://www.regulations.gov* to make submissions or to access the docket, click on the ''Help'' tab at the top of the homepage. Contact the OSHA Docket Office at (202) 693–2350 for information about materials not available through that website and for assistance in using the internet to locate submissions and other documents in the docket.

Authority and Signature

James S. Frederick, Acting Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice pursuant to 29 U.S.C. 655, 40 U.S.C. 3704, Secretary of Labor's Order No. 8–2020 (85 FR 58393), 5 U.S.C. App. 2, and 29 CFR part 1912.

Signed at Washington, DC, on July 2, 2021.

James S. Frederick,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–14631 Filed 7–8–21; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TIME AND DATE: The Members of the National Council on Disability (NCD) will hold a quarterly business meeting on Thursday, July 22, 2021, 1:00 p.m.—4:00 p.m., Eastern Daylight Time (EDT).

PLACE: This meeting will occur via Zoom videoconference. Registration is not required. Interested parties are encouraged to join the meeting in an attendee status by Zoom Desktop Client, Mobile App, or Telephone to dial-in. Updated information is available on NCD's event page at *https://ncd.gov/events/2021/upcoming-council-meeting*. To join the Zoom webinar, please use the following URL: *https://zoom.us/j/99051495407?pwd=MGpQQitxSnNDVXR6MWpjNnlrVlE3dz09* or enter Webinar ID: 990 5149 5407 in the Zoom app. The Passcode is: 151964.

To join the Council Meeting by telephone, dial one of the preferred numbers listed. The following numbers are (for higher quality, dial a number based on your current location): (669) 900–6833; (408) 638–0968; (312) 626–6799; (346) 248–7799; (253) 215–8782; (646) 876–9923; or (301) 715–8592. You will be prompted to enter the meeting ID 990–5149–5407 and passcode 151964.

In the event of audio disruption or failure, attendees can follow the meeting by accessing the Communication Access Realtime Translation (CART) link provided. CART is text-only translation that occurs real time during the meeting and is not an exact transcript.

MATTERS TO BE CONSIDERED: Following welcome remarks and introductions, the Chairman, Executive Director and Executive Committee will provide reports; followed by a community presentation; a strategic plan presentation; subcommittee updates on policy projects; a schedule of remaining 2021 Council Meetings; and any unfinished business before adjournment.

Agenda: The times provided below are approximations for when each agenda item is anticipated to be discussed (all times Eastern Daylight Time):

Thursday, July 22, 2021

1:00–1:05 p.m.—Welcome and Call to Order
1:05–1:15 p.m.—Chairman's Report
1:15–2:00 p.m.—Executive Director's Report
2:00–2:15 p.m.—Executive Committee Report
2:15–2:45 p.m.—Community Presentation: National Disability Institute
2:45–3:15 p.m.—Strategic Plan Presentation
3:15–3:45 p.m.—Subcommittee Updates
3:45–4:00 p.m.—Schedule of 2021 Council Meetings, unfinished business
4:00 p.m.–Adjourn

Public Comment: There is no in-person public comment session during this council meeting, however the Council is soliciting public comment by email, providing an opportunity to hear from you—individuals, businesses, providers, educators, parents and advocates. Public comment submissions will be reviewed during the meeting and delivered to members of the Council at its conclusion. Your comments are important in bringing to the Council's attention issues and priorities of the disability community. To provide comments, please send an email to *PublicComment@ncd.gov* with the subject line ''Public Comment'' and your name, organization, state, and topic of comment included in the body of your email. Submission should be received no later than July 21 to ensure inclusion.

CONTACT PERSON FOR MORE INFORMATION: Nicholas Sabula, Public Affairs Specialist, NCD, 1331 F Street NW, Suite 850, Washington, DC 20004; 202–272–2004 (V), or *nsabula@ncd.gov.*

Accommodations: An ASL interpreter will be on-camera during the entire meeting, and CART has been arranged for this meeting and will be embedded into the Zoom platform as well as available via streamtext link. The web link to access CART (in English) is: *https://www.streamtext.net/player?event=NCD.* If you require additional accommodations, please notify Anthony Simpson by sending an email to *asimpson.cntr@ncd.gov* as soon as possible and no later than 24 hours prior to the meeting.

Due to last-minute confirmations or cancellations, NCD may substitute items without advance public notice.

Dated: July 7, 2021.

Anne C. Sommers McIntosh,

Executive Director.

[FR Doc. 2021–14764 Filed 7–7–21; 4:15 pm]

BILLING CODE 8421–02–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0137]

Systematic Assessment for How the NRC Addresses Environmental Justice in Its Programs, Policies, and Activities

AGENCY: Nuclear Regulatory Commission.

ACTION: Public meeting and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments as part of its systematic review for how NRC programs, policies, and activities address environmental justice. Specifically, the NRC would like input on how the agency is addressing environmental justice, considering the agency's mission and statutory authority. The information will be used to inform the agency's assessment of how it addresses environmental justice.

DATES: Submit comments by August 23, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. The NRC will hold public meetings related to its assessment. See Section IV Public Meeting, of this document for additional information.

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

- *Telephone:* 301–415–3875.
- *Email: NRC-EJReview@nrc.gov.*
- *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.

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0137. 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.

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: Allen Fetter, Office of the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–8556, email: *Allen.Fetter@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0137 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–2021–0137.

• *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 Staff Requirements Memorandum (SRM)–M210218B, ''Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business, 10:00 a.m., Thursday, February 18, 2021, Video Conference Meeting,'' dated April 23, 2021, which provides direction to the staff or this assessment, is available in ADAMS under Accession No. ML21113A070.

• *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 comment submission via email and phone. Please reference Docket ID NRC–2021–0137 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 comment submissions received via *regulations.gov* 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. Background

The NRC is an independent agency established by the Energy Reorganization Act of 1974 that began operations in 1975 as a successor to the licensing and regulatory activities of the Atomic Energy Commission. The NRC's mission is to license and regulate the Nation's civilian use of radioactive materials to provide reasonable assurance of adequate protection of public health and safety and to promote the common defense and security and to protect the environment. As part of its licensing and regulatory activities, the NRC conducts safety, security, and environmental reviews.

Specifically, with respect to environmental reviews, the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321 *et seq.,* requires all Federal agencies to evaluate the impacts of proposed major actions on the human environment. As part of its responsibilities under NEPA, the NRC considers environmental justice. According to the Commission, ''[t]he term 'environmental justice' refers to the federal policy established in 1994 by Executive Order 12898, which directed federal agencies to identify and address 'disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations.''' *Entergy Nuclear Operations, Inc.* (Indian Point Nuclear Generating Units 2 and 3), CLI–15–6, 81 NRC 340, 369 (2015).

The NRC, as an independent agency, was requested, rather than directed, to comply with Executive Order 12898, and this Executive Order did not, in itself, create new substantive authority for Federal agencies. In a March 31, 1994, letter to President Clinton, NRC Chairman Ivan Selin indicated that the NRC would endeavor to carry out the measures set forth in Executive Order 12898 and the accompanying memorandum as part of the NRC's efforts to comply with NEPA (ADAMS Accession No. ML033210526). As noted in the NRC's 1995 Environmental Justice Strategy (ADAMS Accession No. ML20081K602 (March 24, 1995)), because ''the NRC is not a 'land management' agency, *i.e.,* it neither sites, owns, or manages facilities or properties,'' the NRC determined that Executive Order 12898 would ''primarily apply to [NRC] efforts to fulfill'' NEPA requirements as part of NRC's licensing process.

On August 24, 2004, following public comment on a draft Policy Statement (68 FR 62642), the Commission issued its ''Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions'' (69 FR 52040). The purpose of this Policy Statement was to set forth a ''comprehensive statement of the Commission's policy on the treatment of environmental justice matters in NRC regulatory and licensing actions.'' *Id.* at 52,041. The Policy Statement explains that the focus of an environmental justice review ''should be on identifying and weighing disproportionately significant and adverse environmental impacts on minority and low-income populations that may be different from the impacts on the general population. It is not a broad-ranging or even limited review of racial or economic discrimination.'' *Id.* at 52,047.

The Policy Statement also reiterates guidance on defining the geographic area for environmental justice assessments and identifying low-income and minority communities. *Id.* In addition, it explains that a scoping process is used to ''assist the NRC in ensuring that minority and low-income communities, including transient populations, affected by the proposed action are not overlooked in assessing the potential for significant impacts unique to those communities.'' *Id.* at 52,048. In performing a NEPA analysis, ''published demographic data, community interviews and public input through well-noticed public scoping meetings should be used in identifying minority and low-income communities

that may be subject to adverse environmental impacts.'' *Id.*

On April 23, 2021, in a Staff Requirements Memorandum (ADAMS Accession No. ML21113A070), the Commission directed the staff to ''systematically review how the agency's programs, polices, and activities address environmental justice.'' As part of this review, the Commission directed the staff to evaluate recent Executive Orders and assess whether environmental justice is appropriately considered and addressed in the agency's programs, policies, and activities, given the agency's mission. As directed, the staff will consider the practices of other Federal, State, and Tribal agencies and evaluate whether the NRC should incorporate environmental justice beyond implementation through NEPA. The staff will also review the adequacy of the 2004 Policy Statement. The Commission further directed the staff to consider whether establishing formal mechanisms to gather external stakeholder input would benefit any future environmental justice efforts. To carry out the Commission's direction, the staff is seeking to engage stakeholders and interested persons representing a broad range of perspectives. This **Federal Register** notice and the meetings referenced herein are part of this engagement effort.

III. Requested Information and Comments

The NRC is interested in obtaining a broad range of perspectives from stakeholders and interested persons. The focus of this request is to gather information to inform a systematic assessment for how the NRC addresses environmental justice in its programs, policies, and activities, considering the agency's mission and statutory authority. The NRC is particularly interested in receiving input on the following questions:

(1) What is your understanding of what is meant by environmental justice at the NRC?

(2) As described in the Commission's 2004 Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions (69 FR 52040), the NRC currently addresses environmental justice in its NEPA reviews to determine if a proposed agency action will have disproportionately high and adverse impacts on minority and low-income communities, defined as environmental justice communities.

(a) When the NRC is conducting licensing and other regulatory reviews, the agency uses a variety of ways to gather information from stakeholders and interested persons on environmental impacts of the proposed agency action, such as in-person and virtual meetings, **Federal Register** notices requesting input, and dialog with community organizations.

(i) How could the NRC expand how it engages and gathers input?

(ii) What formal tools might there be to enhance information gathering from stakeholders and interested persons in NRC's programs, policies, and activities?

(iii) Can you describe any challenges that may affect your ability to engage with the NRC on environmental justice issues?

(b) How could the NRC enhance opportunities for members of environmental justice communities to participate in licensing and regulatory activities, including the identification of impacts and other environmental justice concerns?

(c) What ways could the NRC enhance identification of environmental justice communities?

(d) What has the NRC historically done well, or currently does well that we could do more of or expand with respect to environmental justice in our programs, policies, and activities, including engagement efforts? In your view, what portions of the 2004 Policy Statement are effective?

(3) What actions could the NRC take to enhance consideration of environmental justice in the NRC's programs, policies and activities and agency decision-making, considering the agency's mission and statutory authority?

(a) Would you recommend that NRC consider any particular organization's environmental justice program(s) in its assessment?

(b) Looking to other Federal, State, and Tribal agencies' environmental justice programs, what actions could the NRC take to enhance consideration of environmental justice in the NRC's programs, policies, and activities?

(c) Considering recent Executive Orders on environmental justice, what actions could the NRC take to enhance consideration of environmental justice in the NRC's programs, policies, and activities?

(d) Are there opportunities to expand consideration of environmental justice in NRC programs, policies, and activities, considering the agency's mission? If so, what are they?

IV. Public Meeting Information

The NRC plans to hold public meetings during the public comment period for this action. The first public meetings are currently planned for July 15, 2021, from 1:30 p.m.–3:00 p.m. ET and 8:00 p.m.–9:30 p.m. ET, via webinar. The public meetings will provide forums for the NRC staff to discuss issues and questions with stakeholders and interested persons. During the public meetings, the NRC does not intend to provide responses to comments submitted during the public meetings. The public meetings were noticed on the NRC's public meeting website. Members of the public should monitor the NRC's public meeting website for additional information about the public meetings at *https://www.nrc.gov/public-involve/public-meetings/index.cfm.* The NRC will post notices for additional public meetings associated with this effort and may post additional material related to this action to the Federal Rulemaking website at *https://www.regulations.gov/* under Docket ID NRC–2021–0137.

Dated: July 6, 2021.

For the Nuclear Regulatory Commission.

Gregory F. Suber,

Director, Environmental Justice Review Team, Office of the Executive Director for Operations.

[FR Doc. 2021–14673 Filed 7–8–21; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92320; File No. SR–NYSEArca–2021–28]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade the Shares of ConvexityShares Daily 1.5x SPIKES Futures ETF Under NYSE Arca Rule 8.200–E (Trust Issued Receipts)

July 2, 2021.

On May 13, 2021, NYSE Arca, Inc. (''NYSE Arca'') 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 of the ConvexityShares Daily 1.5x SPIKES Futures ETF under NYSE Arca Rule 8.200–E, Commentary .02 (Trust Issued Receipts). The proposed rule change was published for comment in the **Federal Register** on May 26, 2021.[3] The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91949 (May 20, 2021), 86 FR 28420.

Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 10, 2021. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates August 24, 2021 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2021–28).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–14606 Filed 7–8–21; 8:45 am]

BILLING CODE 8011–01–P

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34322; 812–15187]

New Age Alpha Trust and New Age Alpha Advisors, LLC

July 6, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act, as well as from certain disclosure requirements in rule 20a-1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934 (''1934 Act''), and sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements'').

APPLICANTS: New Age Alpha Trust (''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series (each a ''Fund'') and New Age Alpha Advisors, LLC (''Initial Adviser''), a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act'') that serves an investment adviser to the Funds (collectively with the Trust, the ''Applicants'').

SUMMARY OF APPLICATION: The requested exemption would permit Applicants to enter into and materially amend subadvisory agreements with subadvisers without shareholder approval and would grant relief from the Disclosure Requirements as they relate to fees paid to the subadvisers.

FILING DATES: The application was filed on December 23, 2020 and amended on April 6, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on August 2, 2021, and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: *msemack@newagealpha.com.*

FOR FURTHER INFORMATION CONTACT: Asaf Barouk, Attorney-Advisor, at (202) 551–4029, or Parisa Haghshenas, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number or an Applicant using the ''Company'' name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

I. Requested Exemptive Relief

1. Applicants request an order to permit the Adviser,[1] subject to the approval of the board of trustees of the Trust (collectively, the ''Board''),[2] including a majority of the trustees who are not ''interested persons'' of the Trust or the Adviser, as defined in section 2(a)(19) of the Act (the ''Independent Trustees''), without obtaining shareholder approval, to: (i) Select investment subadvisers (''Subadvisers'') for all or a portion of the assets of one or more of the Funds pursuant to an investment subadvisory agreement with each Subadviser (each a ''Subadvisory Agreement''); and (ii) materially amend Subadvisory Agreements with the Subadvisers.

2. Applicants also request an order exempting the Subadvised Funds (as defined below) from the Disclosure Requirements, which require each Fund to disclose fees paid to a Subadviser. Applicants seek relief to permit each Subadvised Fund to disclose (as a dollar amount and a percentage of the Subadvised Fund's net assets): (i) The aggregate fees paid to the Adviser and any Wholly-Owned Subadvisers; and (ii) the aggregate fees paid to Affiliated and Non-Affiliated Subadvisers (''Aggregate Fee Disclosure'').[3] Applicants seek an exemption to permit

[1] The term ''Adviser'' means (i) the Initial Adviser, (ii) its successors, and (iii) any entity controlling, controlled by or under common control with, the Initial Adviser or its successors that serves as the primary adviser to a Subadvised Fund. For the purposes of the requested order, ''successor'' is limited to an entity or entities that result from a reorganization into another jurisdiction or a change in the type of business organization. Any other Adviser also will be registered with the Commission as an investment adviser under the Advisers Act.

[2] The term ''Board'' also includes the board of trustees or directors of a future Subadvised Fund (as defined below), if different from the board of trustees (''Trustees'') of the Trust.

[3] A ''Wholly-Owned Subadviser'' is any investment adviser that is (1) an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the Adviser, (2) a ''sister company'' of the Adviser that is an indirect or direct ''wholly-owned subsidiary'' of the same company that indirectly or directly wholly owns the Adviser (the Adviser's ''parent company''), or (3) a parent company of the Adviser. An ''Affiliated Subadviser'' is any investment subadviser that is not a Wholly-Owned Subadviser, but is an ''affiliated person'' (as defined in section 2(a)(3) of the Act) of a Subadvised Fund or the Adviser for reasons other than serving as investment subadviser to one or more Funds. A ''Non-Affiliated Subadviser'' is any investment adviser that is not an ''affiliated person'' (as defined in the Act) of a Fund or the Adviser, except to the extent that an affiliation arises solely because the Subadviser serves as a subadviser to one or more Funds.

a Subadvised Fund to include only the Aggregate Fee Disclosure.[4]

3. Applicants request that the relief apply to Applicants, as well as to any other existing or future registered open-end management investment company or series thereof that intends to rely on the requested order in the future and that: (i) Is advised by the Adviser; (ii) uses the multi-manager structure described in the application; and (iii) complies with the terms and conditions of the application (each, a ''Subadvised Fund'').[5]

II. Management of the Subadvised Funds

4. The Adviser serves or will serve as the investment adviser to each Subadvised Fund pursuant to an investment advisory agreement with the Fund (each an ''Investment Advisory Agreement''). Each Investment Advisory Agreement has been or will be approved by the Board, including a majority of the Independent Trustees, and by the shareholders of the relevant Subadvised Fund in the manner required by sections 15(a) and 15(c) of the Act. The terms of these Investment Advisory Agreements comply or will comply with section 15(a) of the Act. Applicants are not seeking an exemption from the Act with respect to the Investment Advisory Agreements. Pursuant to the terms of each Investment Advisory Agreement, the Adviser, subject to the oversight of the Board, will provide continuous investment management for each Subadvised Fund. For its services to each Subadvised Fund, the Adviser receives or will receive an investment advisory fee from that Fund as specified in the applicable Investment Advisory Agreement.

5. Consistent with the terms of each Investment Advisory Agreement, the Adviser may, subject to the approval of the Board, including a majority of the Independent Trustees, and the shareholders of the applicable Subadvised Fund (if required by applicable law), delegate portfolio management responsibilities of all or a portion of the assets of a Subadvised Fund to a Subadviser. The Adviser will retain overall responsibility for the management and investment of the assets of each Subadvised Fund. This responsibility includes recommending the removal or replacement of Subadvisers, allocating the portion of that Subadvised Fund's assets to any given Subadviser and reallocating those assets as necessary from time to time.[6] The Subadvisers will be ''investment advisers'' to the Subadvised Funds within the meaning of Section 2(a)(20) of the Act and will provide investment management services to the Funds subject to, without limitation, the requirements of Sections 15(c) and 36(b) of the Act.[7] The Subadvisers, subject to the oversight of the Adviser and the Board, will determine the securities and other investments to be purchased, sold or entered into by a Subadvised Fund's portfolio or a portion thereof, and will place orders with brokers or dealers that they select.[8]

6. The Subadvisory Agreements will be approved by the Board, including a majority of the Independent Trustees, in accordance with sections 15(a) and 15(c) of the Act. In addition, the terms of each Subadvisory Agreement will comply fully with the requirements of section 15(a) of the Act. The Adviser may compensate the Subadvisers or the Subadvised Funds may compensate the Subadvisers directly.

7. Subadvised Funds will inform shareholders of the hiring of a new Subadviser pursuant to the following procedures (''Modified Notice and Access Procedures''): (a) Within 90 days after a new Subadviser is hired for any Subadvised Fund, that Fund will send its shareholders either a Multi-manager Notice or a Multi-manager Notice and Multi-manager Information Statement;[9] and (b) the Subadvised Fund will make the Multi-manager Information Statement available on the website identified in the Multi-manager Notice no later than when the Multi-manager Notice (or Multi-manager Notice and Multi-manager Information Statement) is first sent to shareholders, and will maintain it on that website for at least 90 days.[10]

III. Applicable Law

8. Section 15(a) of the Act states, in part, that it is unlawful for any person to act as an investment adviser to a registered investment company ''except pursuant to a written contract, which contract, whether with such registered company or with an investment adviser of such registered company, has been approved by the vote of a majority of the outstanding voting securities of such registered company.''

9. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires a registered investment company to disclose in its statement of additional information the method of computing the ''advisory fee payable'' by the investment company with respect to each investment adviser, including the total dollar amounts that the investment company ''paid to the adviser (aggregated with amounts paid to affiliated advisers, if any), and any advisers who are not affiliated persons of the adviser, under the investment advisory contract for the last three fiscal years.''

10. Rule 20a–1 under the Act requires proxies solicited with respect to a registered investment company to comply with Schedule 14A under the 1934 Act. Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fee,'' a description

[4] Applicants note that all other items required by sections 6–07(2)(a), (b) and (c) of Regulation S–X will be disclosed.

[5] All registered open-end investment companies that currently intend to rely on the requested order are named as Applicants. Any entity that relies on the requested order will do so only in accordance with the terms and conditions contained in the application.

[6] Applicants represent that if the name of any Subadvised Fund contains the name of a subadviser, the name of the Adviser that serves as the primary adviser to the Fund, or a trademark or trade name that is owned by or publicly used to identify the Adviser, will precede the name of the subadviser.

[7] The Subadvisers will be registered with the Commission as an investment adviser under the Advisers Act or not subject to such registration.

[8] A ''Subadviser'' also includes an investment subadviser that will provide the Adviser with a model portfolio reflecting a specific strategy, style or focus with respect to the investment of all or a portion of a Subadvised Fund's assets. The Adviser may use the model portfolio to determine the securities and other instruments to be purchased, sold or entered into by a Subadvised Fund's portfolio or a portion thereof, and place orders with brokers or dealers that it selects.

[9] A ''Multi-manager Notice'' will be modeled on a Notice of internet Availability as defined in Rule 14a–16 under the 1934 Act, and specifically will, among other things: (a) Summarize the relevant information regarding the new Subadviser (except as modified to permit Aggregate Fee Disclosure); (b) inform shareholders that the Multi-manager Information Statement is available on a website; (c) provide the website address; (d) state the time period during which the Multi-manager Information Statement will remain available on that website; (e) provide instructions for accessing and printing the Multi-manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-manager Information Statement may be obtained, without charge, by contacting the Subadvised Fund. A ''Multi-manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the 1934 Act for an information statement, except as modified by the requested order to permit Aggregate Fee Disclosure. Multi-manager Information Statements will be filed with the Commission via the EDGAR system.

[10] In addition, Applicants represent that whenever a Subadviser is hired or terminated, or a Subadvisory Agreement is materially amended, the Subadvised Fund's prospectus and statement of additional information will be supplemented promptly pursuant to rule 497(e) under the Securities Act of 1933.

of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

11. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b), and (c) of Regulation S–X require a registered investment company to include in its financial statements information about investment advisory fees.

12. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that the requested relief meets this standard for the reasons discussed below.

IV. Arguments in Support of the Requested Relief

13. Applicants assert that, from the perspective of the shareholder, the role of the Subadvisers is substantially equivalent to the limited role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants also assert that the shareholders expect the Adviser, subject to review and approval of the Board, to select a Subadviser who is in the best position to achieve the Subadvised Fund's investment objective. Applicants believe that permitting the Adviser to perform the duties for which the shareholders of the Subadvised Fund are paying the Adviser—the selection, oversight and evaluation of the Subadviser—without incurring unnecessary delays or expenses of convening special meetings of shareholders is appropriate and in the interest of the Fund's shareholders, and will allow such Fund to operate more efficiently. Applicants state that each Investment Advisory Agreement will continue to be fully subject to section 15(a) of the Act and approved by the relevant Board, including a majority of the Independent Trustees, in the manner required by section 15(a) and 15(c) of the Act.

14. Applicants submit that the requested relief meets the standards for relief under section 6(c) of the Act. Applicants state that the operation of the Subadvised Fund in the manner described in the Application must be approved by shareholders of that Fund before it may rely on the requested relief. Applicants also state that the proposed conditions to the requested relief are designed to address any potential conflicts of interest or economic incentives, and provide that shareholders are informed when new Subadvisers are hired.

15. Applicants contend that, in the circumstances described in the application, a proxy solicitation to approve the appointment of new Subadvisers provides no more meaningful information to shareholders than the proposed Multi-manager Information Statement. Applicants state that, accordingly, they believe the requested relief is necessary or appropriate in the public interest, and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

16. With respect to the relief permitting Aggregate Fee Disclosure, Applicants assert that disclosure of the individual fees paid to the Subadvisers does not serve any meaningful purpose. Applicants contend that the primary reasons for requiring disclosure of individual fees paid to Subadvisers are to inform shareholders of expenses to be charged by a particular Subadvised Fund and to enable shareholders to compare the fees to those of other comparable investment companies. Applicants believe that the requested relief satisfies these objectives because the Subadvised Fund's overall advisory fee will be fully disclosed and, therefore, shareholders will know what the Subadvised Fund's fees and expenses are and will be able to compare the advisory fees a Subadvised Fund is charged to those of other investment companies. In addition, Applicants assert that the requested relief would benefit shareholders of the Subadvised Fund because it would improve the Adviser's ability to negotiate the fees paid to Subadvisers. In particular, Applicants state that if the Adviser is not required to disclose the Subadvisers' fees to the public, the Adviser may be able to negotiate rates that are below a Subadviser's ''posted'' amounts. Applicants assert that the relief will also encourage Subadvisers to negotiate lower subadvisory fees with the Adviser if the lower fees are not required to be made public.

V. Relief for Affiliated Subadvisers

17. The Commission has granted the requested relief with respect to Wholly-Owned and Non-Affiliated Subadvisers through numerous exemptive orders. The Commission also has extended the requested relief to Affiliated Subadvisers.[11] Applicants state that although the Adviser's judgment in recommending a Subadviser can be affected by certain conflicts, they do not warrant denying the extension of the requested relief to Affiliated Subadvisers. Specifically, the Adviser faces those conflicts in allocating fund assets between itself and a Subadviser, and across Subadvisers, as it has an interest in considering the benefit it will receive, directly or indirectly, from the fee the Subadvised Fund pays for the management of those assets. Applicants also state that to the extent the Adviser has a conflict of interest with respect to the selection of an Affiliated Subadviser, the proposed conditions are protective of shareholder interests by ensuring the Board's independence and providing the Board with the appropriate resources and information to monitor and address conflicts.

18. With respect to the relief permitting Aggregate Fee Disclosure, Applicants assert that it is appropriate to disclose only aggregate fees paid to Affiliated Subadvisers for the same reasons that similar relief has been granted previously with respect to Wholly-Owned and Non-Affiliated Subadvisers.

VI. Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Subadvised Fund may rely on the order requested in the Application, the operation of the Subadvised Fund in the manner described in the Application will be, or has been, approved by a majority of the Subadvised Fund's outstanding voting securities as defined in the Act, or, in the case of a Subadvised Fund whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the initial shareholder before such Subadvised Fund's shares are offered to the public.

2. The prospectus for each Subadvised Fund will disclose the existence, substance and effect of any order granted pursuant to the Application. In addition, each Subadvised Fund will hold itself out to the public as employing the multi-manager structure described in the Application. The prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject

[11] *Carillon Series Trust, et al.,* Investment Co. Act Rel. Nos. 33464 (May 2, 2019) (notice) and 33494 (May 29, 2019) (order).

to oversight by the Board, to oversee the Subadvisers and recommend their hiring, termination, and replacement.

3. The Adviser will provide general management services to each Subadvised Fund, including overall supervisory responsibility for the general management and investment of the Subadvised Fund's assets, and subject to review and oversight of the Board, will (i) set the Subadvised Fund's overall investment strategies, (ii) evaluate, select, and recommend Subadvisers for all or a portion of the Subadvised Fund's assets, (iii) allocate and, when appropriate, reallocate the Subadvised Fund's assets among Subadvisers, (iv) monitor and evaluate the Subadvisers' performance, and (v) implement procedures reasonably designed to ensure that Subadvisers comply with the Subadvised Fund's investment objective, policies and restrictions.

4. Subadvised Funds will inform shareholders of the hiring of a new Subadviser within 90 days after the hiring of the new Subadviser pursuant to the Modified Notice and Access Procedures.

5. At all times, at least a majority of the Board will be Independent Trustees, and the selection and nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

6. Independent Legal Counsel, as defined in Rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

7. Whenever a Subadviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

8. The Board must evaluate any material conflicts that may be present in a subadvisory arrangement. Specifically, whenever a subadviser change is proposed for a Subadvised Fund (''Subadviser Change'') or the Board considers an existing Subadvisory Agreement as part of its annual review process (''Subadviser Review''):

(a) The Adviser will provide the Board, to the extent not already being provided pursuant to section 15(c) of the Act, with all relevant information concerning:

(i) Any material interest in the proposed new Subadviser, in the case of a Subadviser Change, or the Subadviser in the case of a Subadviser Review, held directly or indirectly by the Adviser or a parent or sister company of the Adviser, and any material impact the proposed Subadvisory Agreement may have on that interest;

(ii) any arrangement or understanding in which the Adviser or any parent or sister company of the Adviser is a participant that (A) may have had a material effect on the proposed Subadviser Change or Subadviser Review, or (B) may be materially affected by the proposed Subadviser Change or Subadviser Review;

(iii) any material interest in a Subadviser held directly or indirectly by an officer or Trustee of the Subadvised Fund, or an officer or board member of the Adviser (other than through a pooled investment vehicle not controlled by such person); and

(iv) any other information that may be relevant to the Board in evaluating any potential material conflicts of interest in the proposed Subadviser Change or Subadviser Review.

(b) the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that the Subadviser Change or continuation after Subadviser Review is in the best interests of the Subadvised Fund and its shareholders and, based on the information provided to the Board, does not involve a conflict of interest from which the Adviser, a Subadviser, any officer or Trustee of the Subadvised Fund, or any officer or board member of the Adviser derives an inappropriate advantage.

9. Each Subadvised Fund will disclose in its registration statement the Aggregate Fee Disclosure.

10. In the event that the Commission adopts a rule under the Act providing substantially similar relief to that in the order requested in the Application, the requested order will expire on the effective date of that rule.

11. Any new Subadvisory Agreement or any amendment to an existing Investment Advisory Agreement or Subadvisory Agreement that directly or indirectly results in an increase in the aggregate advisory fee rate payable by the Subadvised Fund will be submitted to the Subadvised Fund's shareholders for approval.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–14651 Filed 7–8–21; 8:45 am]

BILLING CODE 8011–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Suspension of Action: Enforcement of U.S. WTO Rights in the Large Civil Aircraft Dispute

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: On June 15 and June 17, 2021, the United States reached understandings on cooperative frameworks with, respectively, the European Union (EU) and the United Kingdom (UK) regarding the World Trade Organization (WTO) disputes involving large civil aircraft (LCA). In accordance with the understandings reached with the EU and the UK, the U.S. Trade Representative has determined to suspend for a period of five years the action being taken in the Section 301 investigation involving the enforcement of U.S. WTO rights in the LCA dispute.

DATES: The beginning of the five-year suspension period is July 4, 2021, with respect to tariffs on goods of the UK, and July 11, 2021, with respect to tariffs on goods of EU member States.

FOR FURTHER INFORMATION CONTACT: For questions about the investigation or this notice, contact Senior Associate General Counsel Brian Janovitz, at (202) 395–5725, or Director for Europe Michael Rogers, at (202) 395–3320.

SUPPLEMENTARY INFORMATION:

A. Proceedings in the Investigation

For background on the proceedings in this investigation, please see prior notices including: Notice of initiation, 84 FR 15028 (April 12, 2019); notice of determination and action, 84 FR 54245 (October 9, 2019); and notices concerning revisions or modifications of action, 85 FR 10204 (February 21, 2020), 85 FR 50866 (August 18, 2020), 86 FR 674 (January 6, 2021), 86 FR 9420 (February 12, 2021), 86 FR 13961 (March 11, 2021), and 86 FR 14513 (March 16, 2021).

B. Suspension of Action

On June 15 and June 17, 2021, the United States reached similar understandings on cooperative frameworks with the EU and the UK, respectively, regarding trade in large civil aircraft and the parties' WTO disputes. The understandings provide, inter alia, that each party intends to:

- Provide any financing to its LCA producer for the production or development of large civil aircraft on market terms.

• provide any funding for research and development (R&D) for large civil aircraft to its LCA producer through an open and transparent process and intends to make the results of fully government funded R&D widely available, to the extent permitted by law, and intends not to provide R&D funding or other support that is specific, to its LCA producer in a way that would cause negative effects to the other side.

• collaborate on jointly analyzing and addressing non-market practices of third parties that may harm their respective large civil aircraft industries. The two sides will implement the annexed understanding on cooperation on non-market economies through the Working Group.

• suspend application of countermeasures for a period of five years.

To effectuate the suspension of the U.S. countermeasures for the five-year period, the U.S. Trade Representative has determined to terminate the current tariff action and to undertake procedures in advance of the end of the five-year period for the possible re-imposition of tariffs under Section 301.

In particular, pursuant to sections 307(a)(1) and 301(a)(2)(B) of the Trade Act, the U.S. Trade Representative has determined to terminate the current action, which was first imposed in the notice of October 9, 2019 (84 FR 54245) and modified in subsequent notices, effective July 4, 2021, with respect to goods of the UK, and effective July 11, 2021, with respect to goods of EU member States. Pursuant to Section 306 of the Trade Act, and in advance of the end of the five-year suspension period, the U.S. Trade Representative will review implementation by the EU and UK of the framework understandings and their respective measures related to the matters covered in the LCA dispute, and consider a re-imposition of a tariff action under Section 301.

The decision of the U.S Trade Representative to effectuate the five-year suspension in accordance with the framework understandings considers the advice of the interagency Section 301 Committee, advisory committees, and public comments received in response to prior notices issued in the investigation, and consultations with the domestic industry concerned regarding the suspension.

The Annex to this notice modifies the Harmonized Tariff Schedule of the United States to reflect the suspension of the tariff action. The additional duties imposed by subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.49, 9903.89.50 and 9903.89.55, and as provided by their associated subchapter notes, will not apply to products of the UK that are entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on July 4, 2021. The additional duties imposed by subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.37, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.52, 9903.89.55, 9903.89.57, 9903.89.59, 9903.89.61, and 9903.89.63, and as provided by their associated subchapter notes, will not apply to products of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, or Sweden that are entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on July 11, 2021.

Any product of the UK that was admitted into a U.S. foreign trade zone in 'privileged foreign status' as defined in 19 CFR 146.41, before 12:01 a.m. eastern standard time on March 4, 2011, will remain subject to the applicable duties in subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.49, 9903.89.50 and 9903.89.55 upon entry for consumption. Any product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, or Sweden, that was admitted into a U.S. foreign trade zone in 'privileged foreign status' as defined in 19 CFR 146.41, before 12:01 a.m. eastern standard time on March 11, 2021, will remain subject to the applicable duties in subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.37, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.52, 9903.89.55, 9903.89.57, 9903.89.59, 9903.89.61, and 9903.89.63 upon entry for consumption.

Any product of the UK covered by paragraph 3 of the Annex to this notice, that is admitted into a U.S. foreign trade zone on or after 12:01 a.m. eastern daylight time on July 4, 2021, and any product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, or Sweden, covered by paragraph 3 of the Annex to this notice, that is admitted into a U.S. foreign trade zone on or after 12:01 a.m. eastern daylight time on July 11, 2021, may be admitted in any status, as applicable, as defined in 19 CFR 146, Subpart D.

In accordance with section 306 of the Trade Act, in addition to the five-year review, the U.S. Trade Representative will monitor implementation by the EU and UK of the framework understandings and their respective measures related to the matters covered in the LCA dispute, including whether the EU or UK provides new financing to an LCA producer for the production or development of LCA that is not on market terms. If USTR considers that the implementation of the framework understandings or measures related to the WTO dispute are not satisfactory, then USTR will take the most effective action under Section 301 to enforce U.S. WTO rights, which could include the re-imposition of duties.

Annex

1. The additional duties imposed by subheadings 9903.89.05 through 9903.89.63 of the Harmonized Tariff Schedule of the United States (HTSUS), and as provided by their associated subchapter notes, on products of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden or the United Kingdom are terminated as follows. For entries from the United Kingdom, the termination is effective for entries on or after July 4, 2021. For entries from Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, or Sweden the termination is effective for entries on or after July 11, 2021.

2. Note 21(a) to subchapter III of chapter 99 of the HTSUS is modified by deleting ''notes 21(u) and 21(v) of this subdivision,'' and by inserting ''notes 21(u), 21(v), 21(w) and 21(x) of this subdivision,'' in lieu thereof.

3. Note 21 to subchapter III of chapter 99 of the HTSUS is modified by inserting the following new subchapter notes in alphabetical order:

''(w) The U.S. Trade Representative has determined that the additional duties imposed by subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.49, 9903.89.50 and 9903.89.55, and as provided by their associated subchapter notes, shall not apply to articles the product of the United Kingdom that are entered on or after 12:01 a.m. eastern daylight time on or after July 4, 2021.''

''(x) The U.S. Trade Representative has determined that additional duties imposed by subheadings 9903.89.05, 9903.89.07, 9903.89.10, 9903.89.13, 9903.89.16, 9903.89.19, 9903.89.22, 9903.89.25, 9903.89.28, 9903.89.31, 9903.89.34, 9903.89.37, 9903.89.40, 9903.89.43, 9903.89.46, 9903.89.52, 9903.89.55, 9903.89.57, 9903.89.59, 9903.89.61, and 9903.89.63, and as provided by their associated subchapter notes, shall not apply to articles the product of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, or Sweden that are entered on or after 12:01 a.m. eastern daylight time on or after July 11, 2021.''

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–14550 Filed 7–8–21; 8:45 am]

BILLING CODE 3290–F1–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Reallocation of Unused Fiscal Year 2021 WTO Tariff-Rate Quota Volume for Raw Cane Sugar

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country reallocations of the fiscal year (FY) 2021 in-quota quantity of the World Trade Organization (WTO) tariff-rate quota (TRQ) for imported raw cane sugar.

DATES: The changes made by this notice are applicable as of July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Erin Nicholson, Office of Agricultural Affairs, at 202–395–9419 or *erin.h.nicholson@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTSUS), the United States maintains WTO TRQs for imports of raw cane and refined sugar. Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the U.S. Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On July 9, 2020, the Secretary of Agriculture established the FY 2021 TRQ for imported raw cane sugar at the minimum to which the United States is committed pursuant to the WTO Uruguay Round Agreements (1,117,195 metric tons raw value (MTRV) conversion factor: 1 metric ton = 1.10231125 short tons). On July 22, 2020, USTR provided notice of country-by-country allocations of the FY 2021 in-quota quantity of the WTO TRQ for imported raw cane sugar. *See* 85 FR 44353. Based on consultation with quota holders, the U.S. Trade Representative has determined to reallocate 76,571 MTRV of the original TRQ quantity from those countries that have stated they do not plan to fill their FY 2021 allocated raw cane sugar quantities. The U.S. Trade Representative is allocating the 76,571 MTRV to the following countries in the amounts specified below:

Country	FY 2021 raw sugar unused reallocation (MTRV)
Argentina	3,962
Australia	7,648
Belize	1,014
Bolivia	737
Brazil	13,361
Colombia	2,211
Costa Rica	1,381
Dominican Republic	16,217
Ecuador	1,014
El Salvador	2,396
Eswatini (Swaziland)	1,474
Fiji	829
Guatemala	4,423
Guyana	1,106
Honduras	921
India	737
Jamaica	1,014
Malawi	921
Mauritius	1,106
Mozambique	1,199
Nicaragua	1,935
Panama	2,672
Peru	3,778
South Africa	2,119
Thailand	1,290
Zimbabwe	1,106

These allocations are based on the countries' historical shipments to the United States. The allocations of the raw cane sugar WTO TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin. Certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–14659 Filed 7–8–21; 8:45 am]

BILLING CODE 3290–F1–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Supplemental Type Certificates ST03718AT, SA03654AT; Original Product Type Certificate Numbers A32NM, T00006LA, A4SW

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Surrendered supplemental type certificate.

SUMMARY: This notice announces that Avenger Aerospace Solutions, Inc. has surrendered its supplement type certificates, ST03718AT and SA03654AT to the FAA. In accordance with policy, the FAA announces surrender of aircraft certificates in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Send correspondence on this issue to: Federal Aviation Administration, Atlanta Aircraft Certification Branch, 1701 Columbia Avenue, College Park, GA 30337. ATTN: John R. Marshall. All letters must be certified and signed. You may also contact John R. Marshall by phone at (404) 474–5524, or electronically at *john.r.marshall@faa.gov.*

SUPPLEMENTARY INFORMATION: Avenger Aerospace Solutions, Inc. notified the FAA by letter received October 26, 2020, that it is voluntarily surrendering the following supplemental type certificates (STCs):

STC No.	Description of type design change	Associated type certificate No.
ST03718AT	Incorporation of P3A Airworthiness Limitation Section for aircraft operated in Restricted Category for the special mission of aerial dispensing of liquids in accordance with Avenger Aircraft and Services Report No. AAS–MDL–09–002, Revision NC dated April 30, 2009, or later FAA approved revision.	A32NM, T00006LA.
SA03654AT	Installation of Avenger Extended Performance Front Spar Enhancement Kit (new wing front spar lower caps, center splice, and doublers) in accordance with Part II of Avenger Master Data List AAS–MDL–08–001, Revision B, dated November 26, 2008, or later FAA approved revision.	A4SW.

Issued in Fort Worth, TX, on July 1, 2021.

Ross A. Landes,

Aviation Safety, Acting Director, Compliance and Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–14647 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0215]

Agency Information Collection Activities; Renewal of an Approved Information Collection Request: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Transportation (DOT).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. FMCSA requests renewal of an approved ICR titled, ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.'' This ICR allows for ongoing, collaborative and actionable communication between FMCSA and its customers and stakeholders. It also allows feedback to contribute directly to the improvement of program management.

DATES: Please send your comments by August 9, 2021. OMB must receive your comments by this date in order to act quickly on the ICR.

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: Mr. Dan Britton, Mathematical Statistician, FMCSA, Office of Research, Department of Transportation, Federal Motor Carrier Safety Administration, 6th Floor, West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Telephone: 202–366–9980; Email Address: *dan.britton@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 2126–0049.

Type of Request: Renewal of an approved information collection.

Respondents: State and local agencies, the general public and stakeholders, original equipment manufacturers and suppliers to the commercial motor vehicle (CMV) industry, CMV fleet owners, CMV owner-operators, state CMV safety agencies, research organizations and contractors, news organizations, safety advocacy groups, and other Federal agencies.

Estimated Number of Respondents: 9,270.

Estimated Time per Response: Range from 5 to 30 minutes.

Expiration Date: August 31, 2021.

Frequency of Response: Generally, on an annual basis.

Estimated Total Annual Burden: 2,233 hours.

Background

Executive Order 12862, ''Setting Customer Service Standards,'' directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector (58 FR 48257, Sept. 11, 1993). In order to work continuously to ensure that our programs are effective and meet our customers' needs, FMCSA seeks to extend OMB approval of a generic clearance to collect qualitative feedback from our customers on our service delivery. The surveys covered in this generic clearance provide a way for FMCSA to collect this data directly from our customers.

The proposed future information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient and satisfying experience with FMCSA's programs.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;

• Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
• Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
• Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
• Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

A 60-day notice for public comment was published on February 12, 2021 (86 FR 9422). The comment period for that notice closed on April 13, 2021, and a total of one comment was received. The comment was received from the National School Transportation Association, who was supportive of the efforts contained within this ICR. No changes were made to the ICR based on this comment.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority delegated in 49 CFR 1.87.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–14620 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0226]

Agency Information Collection Activities; Revision of a Currently-Approved Information Collection Request: Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. The purpose of this ICR titled, ''Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers,'' requires foreign (Mexico-based) for-hire and private motor carriers to file an application Form OP–2 if they wish to register to transport property only within municipalities in the United States on the U.S.-Mexico international borders or within the commercial zones of such municipalities.

DATES: Please send your comments by August 9, 2021. OMB must receive your comments by this date in order to act quickly on the ICR.

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: Ms. Dora Tambo-Gonzales, Office of Registration, Licensing and Insurance Division, Department of Transportation, Federal Motor Carrier Safety Administration, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–366–2577; email: *dora.tambo.gonzales@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers.

OMB Control Number: 2126–0019.

Type of Request: Renewal of a currently-approved information collection.

Respondents: Foreign motor carriers.

Estimated Number of Respondents: 31.

Estimated Time per Response: 1.5 hours to complete or update Form OP–2.

Expiration Date: October 31, 2021.

Frequency of Response: Occasionally.

Estimated Total Annual Burden: 47 hours [31 responses × 1½ hours to complete Form OP–2 = 47 hours].

Background: Title 49 U.S.C. 13902(c) contains basic licensing procedures for registering foreign (Mexico-based) motor carriers to operate across the U.S.-Mexico international border into the United States. 49 CFR part 368 contains the regulations that require foreign (Mexico-based) motor carriers to apply to the FMCSA for a Certificate of Registration to provide interstate transportation in municipalities in the United States on the U.S.-Mexico international border or within the commercial zones of such municipalities as defined in 49 U.S.C. 13902(c)(4)(A). The FMCSA carries out this registration program under authority delegated by the Secretary of Transportation.

Foreign (Mexico-based) motor carriers use Form OP–2 to apply for Certificate of Registration authority with the FMCSA. The form requests information on the foreign motor carrier's name, address, U.S. DOT Number, form of business (*e.g.,* corporation, sole proprietorship, partnership), locations where the applicant plans to operate, types of registration requested (*e.g.,* for-hire motor carrier, household goods carrier, motor private carrier), insurance, safety certifications, household goods arbitration certifications, and compliance

certifications. FMCSA published a 60-day notice in the **Federal Register** on February 12, 2021, (86 FR 9423), announcing the Agency's intent to submit the *Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers* to OMB for approval, and requesting comments from the public. No comments were received.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority delegated in 49 CFR 1.87.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–14621 Filed 7–8–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 2587

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning application for special enrollment examination.

DATES: Written comments should be received on or before September 7, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (737) 800–6149 or through the internet, at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Special Enrollment Examination.

OMB Number: 1545–0949.

Form Number: Form 2587.

Abstract: Filers use this form to apply to take the Special Enrollment Examination to establish eligibility for enrollment to practice before the Internal Revenue Service.

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: Individuals or households.

Estimated Number of Respondents: 15,643.

Estimated Time per Respondent: .10 hr.

Estimated Total Annual Burden Hours: 1,564.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 6, 2021.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2021–14619 Filed 7–8–21; 8:45 am]

BILLING CODE 4830–01–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meeting Notice; Unified Carrier Registration Plan Board Subcommittee Meeting

TIME AND DATE: July 15, 2021, 12:00 p.m. to 2:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll) or (ii) 1–877–853–5247 (US Toll Free) or 1–888–788–0099 (US Toll Free), Meeting ID: 967 8846 9785, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/j/96788469785.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Finance Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Agenda will be reviewed, and the Subcommittee will consider adoption of the agenda.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Subcommittee Minutes From the May 13, 2021 Subcommittee Meeting—Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the May 13, 2021 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

V. UCR Pilot Projects 2021/2022—UCR Executive Director and DSL Transportation Services, Inc. (''DSL'')

For Discussion and Possible Subcommittee Action

The UCR Executive Director and DSL will lead a discussion regarding potential pilot projects that the UCR may pursue to optimize registration compliance. The Subcommittee may take action to recommend to the UCR Board proceeding with one or more pilot projects.

VI. Review of 2021 Administrative Expenses—UCR Depository Manager

The UCR Depository Manager will review the expenditures of the UCR Plan for the first six months ended June 30, 2021 with the Subcommittee.

VII. Review of 2022 Administrative Budget—UCR Depository Manager

The UCR Depository Manager will lead a discussion regarding the initial preparation of the 2022 UCR administrative budget.

VIII. 2023 Fee Change Recommendation—Subcommittee Chair and UCR Depository Manager

For Discussion and Possible Subcommittee Action

The Subcommittee Chair and the UCR Depository Manager will lead a discussion regarding the results of an analysis of actual and forecasted 2021 registration year revenue data for the purpose of making a fee change proposal to the UCR Board for the 2023 registration year. In addition, the discussion may include potential adjustments to the 2023 administrative operating budget that could impact the fee change calculations. The Subcommittee may take action to make a proposal to the UCR Board of Directors regarding a fee change recommendation for the 2023 UCR registration year.

IX. Maturing of Certificate of Deposit (''CD'')—UCR Depository Manager

For Discussion and Possible Subcommittee Action

The UCR Depository Manager will provide an update on the CD which matures in August 2021. The Subcommittee may take action to recommend a plan to the Board for reinvesting the proceeds.

X. Other Business—Subcommittee Chair

The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

XI. Adjournment—Subcommittee Chair

The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, July 7, 2021 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2021–14744 Filed 7–7–21; 4:15 pm]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app.2, that a meeting of the Rehabilitation Research and Development Service Scientific Merit Review Board will be held Wednesday, August 25, 2021, via Webex. The meeting will be held between 1:00–1:30 p.m. EST. The meeting will be partially closed to the public from 1:10–1:30 p.m. EST for the discussion, examination, and reference to the research applications and scientific review. Discussions will involve reference to staff and consultant critiques of research proposals. Discussions will deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research proposals. As provided by Public Law 92–463 subsection 10(d), as amended by Public Law 94–409, closing the committee meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

The objective of the Board is to provide for the fair and equitable selection of the most meritorious research projects for support by VA research funds and to offer advice for research program officials on program priorities and policies. The ultimate objective of the Board is to ensure that the VA Rehabilitation Research and Development program promotes functional independence and improves the quality of life for impaired and disabled Veterans.

Board members advise the Director, Rehabilitation Research and Development Service and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human and animal subjects of Rehabilitation Research and Development proposals. The Board does not consider grants, contracts, or other forms of extramural research.

Members of the public who wish to attend the open portion of the Webex session from 1:00–1:10 p.m. EST may join by dialing the Webex USA Toll-free Number 1–833–558–0712 and entering the meeting number (access code): 199 342 9297.

Written comments from the public must be sent to Tiffany Asqueri, Designated Federal Officer, Rehabilitation Research and Development Service, Department of Veterans Affairs (14RDR), 810 Vermont Avenue NW, Washington, DC 20420, or to *Tiffany.Asqueri@va.gov* prior to the meeting. Those who plan to attend the open portion of the meeting must contact Mrs. Asqueri at least 5 days before the meeting. For further information, please call Mrs. Asqueri at 202–443–5757.

Dated: July 3, 2021.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–14616 Filed 7–8–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0734]

Agency Information Collection Activity Under OMB Review: Report of General Information, Report of First Notice of Death, Report of Nursing Home or Assisted Living Information, Report of Defense Finance and Accounting Service (DFAS), Report of Non-Receipt of Payment, Report of Incarceration, Report of Month of Death

AGENCY: Veterans Benefits Administration (VBA), Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 7, 2021.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy Kessinger, Veterans Benefits Administration (20F), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0734'' 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. 2900–0794'' 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 CFR 3.217.

Title: VA Form 27–0820, Report of General Information, VA Form 27–0820a, Report of Death of First Notice of Death, VA Form 27–0820b, Report of Nursing Home and Assisted Living Information, VA Form 27–0820c, Report of Defense Finance and Accounting Service (DFAS), VA Form 27–0820d, Report of Non-Receipt of Payment, VA Form 27–0820e, Report of Incarceration, VA Form 27–0820f, Report of Month of Death.

OMB Control Number: 2900–0734.

Type of Review: Extension of a currently approved collection.

Abstract: The forms will be used by VA personnel to document verbal information obtained telephonically from claimants or their beneficiary. The data collected will be used as part of the evidence needed to determine the claimant's or beneficiary's eligibility for benefits.

Affected Public: Individuals.

Estimated Annual Burden: 212,500 annual hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 2,550,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–14622 Filed 7–8–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Rehabilitation, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Veterans' Advisory Committee on Rehabilitation (VACOR) will meet virtually on Wednesday, August 4, 2021 and Thursday, August 5, 2021 from 11:00 a.m. to 3:00 p.m. EST. The meeting sessions are open to the public.

The purpose of the Committee is to provide advice to the Secretary of VA on the rehabilitation needs of Veterans with disabilities and on the administration of VA's Veteran rehabilitation programs. The Committee members will continue to receive briefings on employment programs and services designed to enhance the delivery of services for the rehabilitation potential of Veterans and discuss recommendations to be included in the Committee's next annual comprehensive report.

Time will be allocated for receiving oral comments from the public. Members of the public may submit written comments for review by the Committee to Latrese Thompson, Designated Federal Officer, Veterans Benefits Administration (28), 810 Vermont Avenue NW, Washington, DC 20420 or at *Latrese.Thompson@va.gov.* In the communication, writers must identify themselves and state the organization, association or person(s) they represent. For any members of the public that wish to attend virtually, use WebEx link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m9a9bcede8c031636ea67d605367b2b84.*

1 (404) 397–1596 USA Toll Number (access code): 199 948 1819

Meeting password: PTesXmD?442

Dated: July 2, 2021.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–14605 Filed 7–8–21; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 86 Friday,

No. 129 July 9, 2021

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1749–P]

RIN 0938–AU39

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: Proposed rule.

SUMMARY: This proposed rule would update the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2022. This rulemaking also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this rulemaking proposes to update requirements for the ESRD Quality Incentive Program (QIP), including a proposed measure suppression policy for the duration of the coronavirus disease 2019 (COVID–19) public health emergency (PHE) and as well as proposals to suppress individual ESRD QIP measures under that proposed measure suppression policy. This proposed rule also announces an extension of time for facilities to report September through December 2020 ESRD QIP data under our Extraordinary Circumstances Exception (ECE) policy due to CMS operational issues, and proposes to not score facilities or reduce payment to any facility in PY 2022. In addition, this proposed rule includes requests for information on topics that are relevant to the ESRD QIP. Further, this rule also proposes 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. Finally, this proposed rule includes several requests for information to inform payment reform under the ESRD PPS.

DATES: To be assured consideration, comments must be submitted at one of the addresses provided below, by August 31, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1749–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1749–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1749–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

ESRDApplications@cms.hhs.gov, for issues related to 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:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Current Procedural Terminology (CPT) Copyright Notice: Throughout this proposed rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary
- A. Purpose
- B. Summary of the Major Provisions
- C. Summary of Cost and Benefits

II. Calendar Year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
- A. Background
- B. Provisions of the Proposed Rule
- C. Proposed Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2022 Payment

III. Calendar Year (CY) 2022 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)
- A. Background
- B. Proposed Annual Payment Rate Update for CY 2022

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
- A. Background
- B. Extraordinary Circumstances Exception (ECE) Previously Granted for the ESRD QIP and Notification of ECE Due to ESRD Quality Reporting System Issues
- C. Proposed Flexibilities for the ESRD QIP in Response to the COVID–19 PHE
- D. Proposed Special Scoring Methodology and Payment Policy for the PY 2022 ESRD QIP
- E. Proposed Updates to Requirements Beginning With the PY 2024 ESRD QIP
- F. Updates for the PY 2025 ESRD QIP
- G. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

V. End-Stage Renal Disease Treatment Choices (ETC) Model
- A. Background
- B. Provisions of the Proposed Rule
- C. Requests for Information (RFIs) on Topics Relevant to ETC Model

VI. Requests for Information
- A. Informing Payment Reform Under the ESRD PPS

B. Technical Expert Panels (TEPs)
C. Calculation of the Low-Volume Payment Adjustment (LVPA)
D. Calculation of the Case-Mix Adjustments
E. Calculation of the Outlier Payment Adjustment
F. Calculation of the Pediatric Dialysis Payment Adjustment
G. Modifying the ESRD PPS and Hospital Cost Reports
H. Modifying the Pediatric Cost Report
I. Modifying Site of Services Provided to Medicare Beneficiaries with Acute Kidney Injury (AKI)
VII. Collection of Information Requirements
A. Legislative Requirement for Solicitation of Comments
B. Requirements in Regulation Text
C. Additional Information Collection Requirements
VIII. Response to Comments
IX. Economic Analyses
A. Regulatory Impact Analysis
B. Detailed Economic Analysis
C. Accounting Statement
D. Regulatory Flexibility Act Analysis (RFA)
E. Unfunded Mandates Reform Act Analysis (UMRA)
F. Federalism
G. Congressional Review Act
X. Files Available to the Public via the Internet
Regulations Text

I. Executive Summary

A. Purpose

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 proposes updates to 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 proposes to update 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 proposes 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 announcing an extension of time for facilities to report September-December 2020 ESRD QIP data under our Extraordinary Circumstances Exception (ECE) policy due to CMS operational issues. Beginning with the PY 2024 ESRD QIP, we are proposing to update the specifications for the SHR clinical measure. We are also proposing for the PY 2024 ESRD QIP to adopt CY 2019 as the baseline period for purposes of calculating the achievement thresholds, benchmarks, and performance standard values. Although no new requirements are proposed for the PY 2025 ESRD QIP, this proposed rule includes policies that would apply in PY 2025. This proposed rule also includes requests for information on several important topics, including strategies that CMS 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 rulemaking proposes to implement 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 rulemaking proposes 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 proposing to add processes and requirements for ETC Participants to receive certain data from CMS and to include certain additional waivers and flexibilities as part of the ETC Model test. This proposed rule also includes requests for information regarding the placement of peritoneal dialysis catheters and the development of a home dialysis beneficiary experience measure.

B. Summary of the Major Provisions

1. ESRD PPS

• *Update to the ESRD PPS base rate for CY 2022:* The proposed CY 2022 ESRD PPS base rate is $255.55. This proposed amount reflects the application of the wage index budget-neutrality adjustment factor (.999546) and a productivity-adjusted market basket increase of 1.0 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $255.55 (($253.13 × .999546) × 1.010 = $255.55).

• *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 proposing to update 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 proposing to update the outlier policy using the most current data, as well as update 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 proposed FDL amount for pediatric beneficiaries would decrease from $44.78 to $30.38, and the MAP amount would decrease from $30.88 to $28.73, as compared to CY 2021 values. For adult beneficiaries, the proposed FDL amount would decrease from $122.49 to $111.18, and the MAP amount would decrease from $50.92 to $47.87. 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 proposed 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 $9.41. This proposed offset amount reflects the application of the productivity-adjusted market basket increase of 1.0 percent ($9.32 × 1.010 = $9.41).

• *TPNIES applications received for CY 2022:* This proposed rule presents 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.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2022 to $255.55, which is the same as the base rate proposed under the ESRD PPS for CY 2022.

3. ESRD QIP

We are announcing an extension of time for facilities to report September through December 2020 ESRD QIP data under our Extraordinary Circumstances Exception (ECE) policy due to CMS operational issues. We are proposing to adopt a measure suppression policy for the duration of the COVID–19 PHE that would enable 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 proposing to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, and the Long-Term Catheter Rate clinical measure for PY 2022 under the proposed measure suppression policy. Finally, we are proposing to not score or reduce payment to any facility in PY 2022. Beginning with the PY 2024 ESRD QIP, we are proposing to update the specifications for the SHR clinical measure. We are also proposing for the PY 2024 ESRD QIP to adopt CY 2019 as the baseline period for purposes of calculating the achievement thresholds, benchmarks, and performance standard values. This proposed rule also announces the performance standards and payment reductions that would apply for PY 2024. This proposed rule describes several policies continuing for PY 2025, but does not propose any new requirements beginning with the PY 2025 ESRD QIP.

This proposed rule includes requests for public comment on several important topics, including closing the gap in health equity, adding a COVID–19 vaccination measure for health care personnel (HCP) and 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 the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR®) standard.

4. ETC Model

We are proposing to implement 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 propose to modify the methodology for attributing Pre-emptive LDT Beneficiaries to Managing Clinicians, such that a Pre-emptive LDT Beneficiary would 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 propose adding nocturnal in-center dialysis to the calculation of the home dialysis rate for ESRD facilities not owned in whole or in part by a large dialysis organization (LDO) as well as Managing Clinicians.

• *Transplant Rate Beneficiary Exclusion:* To better align with common reasons transplant centers do not place patients on the transplant waitlist, we propose to exclude 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 propose to increase achievement benchmarks by 10 percent over rates observed in Comparison Geographic Areas every two MYs, beginning in MY3 (2022). We also propose to 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 our proposal to stratify achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, we propose to introduce the Health Equity Incentive to the improvement scoring methodology used in calculating the PPA. CMS expects that the Health Equity Incentive would 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 propose to 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 proposing a process by which CMS would share certain model data with ETC Participants.

• *Medicare Waivers:* We are proposing 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: 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.

• *Kidney Disease Patient Education Services Coinsurance Waivers:* We are proposing to 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 anticipate making the determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)), would be available to protect the reduction or elimination of coinsurance performed in accordance with our proposed policy, if finalized.

C. Summary of Costs and Benefits

In section IX.B of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact table in section IX.B.1.a of this proposed 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 proposed CY 2022 changes is projected to be a 1.2 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.3 percent increase in payments compared with freestanding facilities with an estimated 1.2 percent increase. We estimate that the aggregate ESRD PPS expenditures would increase by approximately $140 million in CY 2022 compared to CY 2021. This reflects a $120 million increase from the payment rate update and a $20 million increase due to the updates to the outlier threshold amounts. Because of the projected 1.2 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 1.2 percent in CY 2022, which translates to approximately $30 million.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section IX.B.2.a of this proposed 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 proposed CY 2022 changes is projected to be a 1.0 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 1.1 percent increase in payments compared with freestanding ESRD facilities with an estimated 1.0 percent increase. The overall impact reflects the effects of the updated wage index and the proposed payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the proposed CY 2022 ESRD PPS base rate, would increase by $1 million in CY 2022 compared to CY 2021.

3. Impacts of the Proposed ESRD QIP

Our proposals 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 necessitates 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 proposals impacting the PY 2022 ESRD QIP we are making in this proposed rule, we are modifying our previous estimate. We now estimate that the overall economic impact of the PY 2022 ESRD QIP would be approximately $215 million. The $215 million figure for PY 2022 includes costs associated with the collection of information requirements. If our proposals are finalized as proposed, there would be no payment reductions in PY 2022. We estimate that the overall economic impact of the PY 2024 ESRD QIP would be approximately $232 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The $232 million figure for PY 2024 includes costs associated with the collection of information requirements, which we estimate would be approximately $215 million, and $17 million in estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2025 ESRD QIP would be approximately $232 million as a result of the policies we have previously finalized.

4. Impacts of Proposed Changes to the ETC Model

The impact estimate in section IX.B.4 of this proposed rule describes the estimated change in anticipated Medicare program savings arising from

the ETC Model over the duration of the ETC Model as a result of the changes proposed in this proposed rule. We estimate that the ETC Model would result in $38 million in net savings over the 6.5-year duration of the ETC Model. We also estimate that $7 million of the estimated $38 million in net savings would be attributable to changes proposed in this proposed 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 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. We have codified our definitions 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

1. Proposed CY 2022 ESRD PPS Update

a. Proposed 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 propose 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 propose 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 is 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 note that for CY 2022 and beyond, CMS is 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) is projected to be 0.6 percent.

As a result of these provisions, the proposed CY 2022 ESRD market basket increase factor reduced by the productivity adjustment is 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 are proposing that if more recent data become available after the publication of this 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.

For the CY 2022 ESRD payment update, we propose 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).

b. The Proposed 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 would 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).[1]

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.

For CY 2022, we are proposing to update the ESRD PPS wage index to use the most recent hospital wage data. The proposed 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 proposed 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. Proposed 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.[2] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf*. 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)

[1] We note that for the CY 2020 ESRD PPS final rule, we did not apply the statewide urban average to Carson City, Nevada because hospital data was available to compute the wage index.

[2] 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.

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 propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2020. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we propose 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 recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. As discussed in the CY 2021 ESRD PPS final rule (85 FR 71438), CY 2019 claims data show outlier payments represented approximately 0.5 percent of total payments. As discussed in section II.B.1.c.(1) of this proposed 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 CY 2022, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2020 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2020 claims data. 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 proposed estimates for this rule. The estimates for the proposed CY 2022 outlier policy, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2022 prices for outlier services.

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 Proposed 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	$27.11	$49.72
Adjustments				
Standardization for outlier services	1.0390	0.9789	1.0815	0.9824
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$30.88	$50.92	$28.73	$47.87
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$44.78	$122.49	$30.38	$111.18
Patient-month-facilities qualifying for outlier payment	8.80%	5.15%	11.37%	5.45%

*Note that Column I was obtained from Column II of Table 5 from the CY 2021 ESRD PPS final rule (85 FR 71437).

The estimated FDL amount per treatment that determines the CY 2022 outlier threshold amount for adults (Column II; $111.18) 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 $47.87. For

pediatric patients, there is a decrease in the FDL amount from $44.78 to $30.38. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $30.08 to $28.73.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2022 would be 5.45 percent for adult patients and 11.37 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 noted in past rulemaking, 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 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 note that recalibration of the FDL amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

d. Proposed Impacts to the CY 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 proposing an ESRD PPS base rate for CY 2022 of $255.55. 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 are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 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 proposed rule, the proposed 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 proposed wage index budget-neutrality adjustment factor is .999546. This application would yield a CY 2022 ESRD PPS proposed base rate of $253.02 prior to the application of the proposed market basket increase ($253.13 × .999546 = $253.02).

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 proposed ESRDB market basket percentage increase factor is 1.6 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, the proposed productivity adjustment for CY 2021 is 0.6 percent, thus yielding a proposed update to the base rate of 1.0 percent for CY 2022. Therefore, the CY 2022 ESRD PPS proposed base rate is $255.55 ($253.02 × 1.010 = $255.55).

In summary, we are proposing a CY 2022 ESRD PPS base rate of $255.55. This amount reflects a proposed CY 2022 wage index budget-neutrality adjustment factor of .999546, and the CY 2022 ESRD PPS productivity-adjusted market basket update of 1.0 percent.

e. Update to the Offset Amount for TPNIES

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. We finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to establish the basis of payment of the TPNIES for these capital-related assets that are home dialysis machines when used in the home, including an offset to the pre-adjusted per treatment amount to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. We will pay 65 percent of the MAC-determined preadjusted per treatment amount reduced by an offset for 2-calendar

years. Section § 413.236(f)(3)(v) states that effective January 1, 2022, CMS will annually update the amount determined in paragraph (f)(3)(iv) of § 413.236 by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

The CY 2021 offset amount for TPNIES 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 proposed rule, 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 CY 2021 offset amount results in a proposed CY 2022 offset amount of $9.41($9.32 × 1.010). We will update this calculation to use the most recent data available in the CY 2022 ESRD PPS final rule.

C. Proposed 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 SCI criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at 42 CFR 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 SCI for purposes of the TPNIES under the ESRD PPS based on the IPPS SCI 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 SCI 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 discuss 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 SCI 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 SCI criterion, as the guidance has 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 while in the CY 2020 ESRD PPS proposed rule (84 FR 38354), we stated 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. 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 provide a description of the new home dialysis machine and pertinent facts in the ESRD PPS proposed rule so the public may comment and then publish the results in the ESRD PPS final rule. We will consider whether the new home dialysis machine meets the eligibility criteria specified in the proposed revisions to § 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 will need to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with the proposed revisions to § 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 by requiring 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, and 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) of this chapter; 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. A discussion of these applications is presented below. The applications received are for technologies commonly used for the treatment of ESRD: Hemodialysis (HD) and peritoneal dialysis (PD). Detailed definitions for HD and PD are found in Chapter 11, Section 10 of the Medicare Benefits Policy Manual (Pub. L. 100–02).[3] 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. PD is a process that involves waste products passing from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically.

a. Tablo® System

Outset Medical, Inc. submitted an application for the TPNIES for the Tablo® System (Tablo®) 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 also 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 simple-to-use touchscreen interface; (2) a proprietary, disposable, single-use pre-strung cartridge that easily clicks into place, minimizing steps, touch points, and connections; 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 unique features combine to provide a significantly differentiated HD solution with many benefits. First, the applicant stated that the Tablo® System's intuitive touchscreen interface makes it easy to learn and use, guiding users through treatment from start to finish using step-by-step 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 does 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 is 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 user-friendly pre-strung blood, saline, and infusion tubing and a series of sensor-receptors mounted to a user-friendly organizer snaps easily 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.[4] 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.[5] [6] 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.[7] [8]

[3] Medicare Benefits Policy Manual (Pub. L. 100–102), available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

[4] 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.

[5] 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.

[6] 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.

[7] 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.

[8] Chan, Christopher T. et al. (2018). Exploring Barriers and Potential Solutions in Home Dialysis: An NKF–KDOQI Conference Outcomes Report

Continued

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.[9] The applicant stated that the Tablo® System was designed to address many system-related barriers that result in patients resigning themselves to in-center care and/or stopping home modalities due to the burden of self-managed therapy.

The applicant stated that while 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.[10]

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.[11] 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 demonstrate 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.[12] 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,[13] as compared to 4:1 in Canada.[14]

The applicant asserted that that the Tablo® System presents 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 necessary for the provision of maintenance dialysis and, therefore, we would consider this a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion under § 413.236(b)(2), whether the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the Tablo® System received FDA marketing authorization for home use on March 31, 2020. Therefore, the Tablo® System is considered new. We note that, in reviewing the enclosure to which the March 31, 2020 FDA authorization letter refers, the applicant's Section 510(k) submission indicates that the Tablo® Cartridge was reviewed separately from the Tablo® System and has its own separate 510(k) clearance. As discussed 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 is not new.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

With respect to the third TPNIES eligibility criterion under § 413.236(b)(3), whether the item is commercial available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the Tablo® System became available for home use on April 1, 2020. Therefore, the Tablo® System is commercially available.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

With respect to the fourth TPNIES eligibility criterion under § 413.236(b)(4), whether the applicant submitted a HCPCS Level II code application by the July 6, 2021 deadline, the applicant stated that it intends to submit a HCPCS Level II code application by the deadline.

(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 SCI 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 SCI claims: (1) Decreased treatment frequency with adequate dialysis clearance; (2) increased adherence to dialysis treatment and retention to home therapy; and (3) improved patient

American Journal of Kidney Diseases, Volume 73, Issue 3, 363–371.

[9] 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*.

[10] 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*.

[11] *Ibid*.

[12] 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.

[13] 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.

[14] 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.

quality of life. The applicant supported these claims with the Tablo® Investigational Device Exemption (IDE) Study [15] and secondary support from four papers [16] [17] [18] [19] and two posters.[20] [21] The applicant also provided comparison data from three studies directly related to the incumbent [22] [23] [24] 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.[25]

We provide an overview of these ten sources below, followed by the applicant's summary of how the data support each claim of SCI. We conclude with a discussion of the way in which we have applied the requirements of § 413.236(b)(5) to our review of the application and a summary of our concerns. We have not included 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 SCI Sources

As stated previously, the applicant's primary support for its three SCI claims comes 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® 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® IDE study sample was comprised of a representative cohort of dialysis patients and reports 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® Console fluid removal algorithm, respectively.[26] We clarify 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 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.[27]

Next, an article from Chertow, et al., described additional data from the Tablo® IDE study (discussed previously), including health-related quality of life, to further assess the safety of home HD with the Tablo®

[15] *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.*

[16] 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.

[17] 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.

[18] 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.

[19] 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).

[20] 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.

[21] 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.

[22] 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).

[23] 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.

[24] 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.

[25] 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.

[26] *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.*

[27] 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.

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.[28]

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 distribution range modeled by the authors ranged from 25 to 45 L. Under ideal conditions, the authors demonstrate 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.[29]

Next, an article by Plumb, et al., described the Tablo® 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.[30]

Next, a separate article by Plumb et al., reports additional data from the Tablo® 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

[28] 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.

[29] 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.

[30] 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.

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.[31]

Next, a poster presentation from Chahal et al., reported patient device preference of prior in-home HD patients based on data from the Tablo® IDE study (previously discussed). The authors noted that 13 of the 30 participants in the Tablo® 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.[32]

As stated previously in this section of the proposed rule, the applicant submitted several sources pertaining to the incumbent, NxStage.® First, an article from Kraus et al., describes 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 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.[33]

Second, an article from Finkelstein et al., reports 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.[34]

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 peritoneal dialysis, 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.[35]

[31] 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).

[32] 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.

[33] 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).

[34] 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.

[35] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and

Continued

Fourth, in Suri et al., 1116, daily home HD patients were matched by propensity scores to 2784, contemporaneous USRDS patients receiving home peritoneal dialysis. The authors compared hospitalization rates from cardiovascular, infectious, access-related or bleeding causes, and modality failure risk. Similar analyses were performed for 1187, daily home HD patients matched to 3173, 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 peritoneal dialysis). 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.[36]

(b) Applicant SCI Claims

Regarding the applicant's first claim that the Tablo® System decreases treatment frequency with adequate 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.[37] 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,[38] as compared to NxStage® IDE patients prescribed therapy at 6 days per week.[39]

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.[40] 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[41] 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.,[42] allow 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.[43] 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) are 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.[44] allows the conversion of the kinetic model described into anticipated patient weights. The applicant further stated

technique failure in daily home hemodialysis and matched peritoneal dialysis patients: A matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[36] 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.

[37] 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.

[38] 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.

[39] NxStage Clearance Calculator. Available at: *https://dosingcalculator.nxstage.com/DosingCalculator/*. Accessed on Jan 21, 2021.

[40] 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.

[41] Health Management Associates (HMA) analysis of 2018 100% Medicare Outpatient file.

[42] 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.

[43] *Ibid.*

[44] *Ibid.*

that in calculating with standard blood flow and a higher dialyzer mass transfer area coefficient for urea (KoA) diayzer, 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.[45] [46] The applicant stated that at 44.3 percent of total weight, this volume of distribution of urea correlates 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,[47] 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 Medicare Administrative Contractors (MACs) have discretion in reimbursing additional treatments with medical justification.[48] Per the applicant, an analysis of Medicare claims data from 2018 finds that despite the limitations of the reimbursement policy, Medicare is paying 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.[49] However, 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 note that, as indicated in Local Coverage Determination ID L35014, ''Frequency of Dialysis'' (revised effective September 26, 2019),[50] 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 is 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.[51] [52] Per the applicant, home use of the Tablo® System can reduce the need for a fifth or sixth weekly treatment without increasing patients' symptom burden.[53] The applicant stated that by achieving adequacy targets with fewer treatments, 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.[54] [55] 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® 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 is 1,688 per 1,000 patient-years, and for patients who utilize peritoneal dialysis, the hospitalization rate is 1,460 per 1,000 patient years.[56]

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.,[57] and Suri et al.,[58] report 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 clarify that this would represent 930 to 1,663 cases observed

[45] 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.

[46] 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.

[47] 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.

[48] 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.

[49] Health Management Associates (HMA) analysis of 2018 100 percent Medicare Outpatient file.

[50] 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&*.

[51] National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. *Am J Kidney Dis.* 2015;66(5):884–930.

[52] 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*.

[53] 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.

[54] 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.

[55] 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).

[56] 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.

[57] 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.

[58] 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.

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 can be reasonably assumed that home HD patients were using NxStage® for treatment. The applicant stated that the results from these studies suggest 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 show incremental improvement over the hospitalization rate of the current home HD population.

Regarding the applicant's second claim that the Tablo® System increases 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.[59]

The applicant stated that adherence to prescribed dialysis treatments is crucial for dialysis patients because missed treatments increases the risk of dialysis dropout, hospitalization, and death.[60] Per the applicant, the Tablo® IDE study demonstrated a 99 percent treatment adherence rate to all prescribed home treatments[61] 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.[62] Per the applicant, using a comparable metric of missing 5 or fewer of all possible treatments at home, Tablo® 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.[63] The applicant stated that this is challenging for the patient and taxing on the healthcare system that has 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.[64] The applicant stated that in comparison, 81 percent of participants completed the NxStage® IDE study.[65]

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.[66] Per the applicant, published NxStage® IDE data[67] 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 will 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,[68] care partner burnout and a patient's perception of being a burden is associated with discontinuation of home therapy.[69] [70] Per the applicant, the 28 patients who entered the home phase of the Tablo® 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 clarify that per Plumb, et al.,[71] this

[59] 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.

[60] 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.

[61] 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.

[62] 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.

[63] 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.

[64] 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.

[65] 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.

[66] 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).

[67] 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).

[68] 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).

[69] 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.

[70] 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.

[71] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell,

is the baseline percentage and reflects 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 is a 39 percent reduction from baseline NxStage® use; and only 18 percent of these instances related to use of the Tablo® System, which is a 61 percent reduction in rate from baseline NxStage® use.[72]

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.[73] 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).[74] Per the applicant, these data underscore 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 contribute 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 the Tablo® System correlated to the improved retention and adherence rates in the Tablo® IDE study. The applicant stated that on a population level, this likely translates 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 represents an improvement with respect to burden and monitoring as compared to NxStage®.

Regarding the applicant's third claim that the Tablo® System improves patient quality of life, the applicant stated that patients on the Tablo® System experience 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.[75] Per the applicant, the Tablo® 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.[76] 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[77] 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 provides 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.[78]

Per the applicant, patients in the Tablo® IDE study reported mean EQ–5D index values of 0.821 (SD: ±0.163)[79] 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® 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® 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 peritoneal dialysis.

The applicant stated that sleep problems are present in 60 percent of patients with chronic kidney disease (CKD) and ESRD[80] and that patients rank fatigue and lack of energy as the most important contributor to their decreased quality of life.[81] Per the

Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[72] *Ibid.*

[73] 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.

[74] 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.

[75] 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.

[76] 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.

[77] 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.

[78] 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.

[79] 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.

[80] 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.

[81] Urquhart-Secord, Rachel et al. (2016). Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group

Continued

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® 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.[82] [83] 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.[84] 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.

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.[85] Per the applicant, participants in the Tablo® 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 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.[86] 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.[87]

The applicant concluded by asserting that the totality of evidence submitted in support of the Tablo® System demonstrates SCI 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.[88] 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® 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.[89]

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 Preliminary Assessment of SCI Claims and Sources

After a review of the information provided by the applicant, we have identified the following concerns regarding the SCI eligibility criterion for the TPNIES. We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether Tablo® meets the SCI criterion and other eligibility criteria for the TPNIES in the 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 note that the Tablo® IDE study did not test whether patients receive adequate dialysis on a thrice-weekly schedule. Instead, data published from the Tablo® IDE study address 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 affirm the results from the modeling study. We also note that the authors in Alvarez et al.[90] stated that conclusions about fluid removal could not be made from their study. We would be interested in whether additional studies are available that address issues related to effective fluid removal using home

Technique Study American Journal of Kidney Diseases, Volume 68, Issue 3, 444–454.

[82] 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.

[83] Natale, V., Fabbri, M., Tonetti, L., & Martoni, M. (2014). Psychometric goodness of the mini sleep questionnaire. Psychiatry and clinical neurosciences, 68(7), 568–573.

[84] 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.

[85] 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.

[86] 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.

[87] 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.

[88] 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.

[89] 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.

[90] 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.

self-care dialysis thrice-weekly with the Tablo® System. We invite comments on whether less frequent dialysis sessions would represent SCI over shorter, more frequent sessions that, according to the applicant, are common among users of the incumbent technology.

The applicant's second claim was that the Tablo® System increases 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® 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® 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® IDE study, it does not appear that the sources [91] [92] published these hospitalization rates. We further note that the applicant relied on historical comparisons in asserting that that patients treated with the Tablo® System experience reduced disease burden and improved quality of life.

We note that in the Tablo® 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® IDE study.

We understand 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 invite comments on whether this potential benefit represents SCI, including whether the Tablo® System represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries.

(6) Capital Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), whether the item is a capital-related asset and home dialysis machine, § 413.236(a)(2) defines these terms. First, a capital-related asset is an asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets. Second, home dialysis machines are HD machines and PD cyclers in their entirety (meaning that one new part of a machine does not make the entire capital-related asset new) that receive FDA marketing authorization for home use and when used in the home for a single patient. 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. Therefore, the Tablo® System is a capital-related asset that is a home dialysis machine. We welcome comments on the Tablo® System's status as a capital related asset that is a home dialysis machine.

b. CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System)

CloudCath submitted an application for the TPNIES for the CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) for CY 2022. According to the application, the CloudCath System is a tabletop passive drainage system that detects and monitors solid particles in dialysate effluent during PD treatments. Solid particles in dialysate effluent, manifesting itself as cloudy dialysate, may indicate that the patient has peritonitis, the inflammation of the peritoneum in the abdominal wall usually due to a bacterial or fungal infection.[93] PD therapy is a common cause of peritonitis.[94] If left untreated, the condition can be life threatening.[95]

PD-related peritonitis is a major complication and challenge to the long-term success and adherence of patients on PD therapy.[96] The applicant stated that only about 12 percent of eligible patients are on PD therapy.[97] The applicant claimed that the risk of PD-related peritonitis, and the challenges to detect it, are the main reasons for these figures. The guidelines for diagnosis of PD-related peritonitis, as outlined by the International Society for Peritoneal Dialysis (ISPD), recommend that peritonitis be diagnosed when at least 2 of the following criteria are present: (1) The patient experiences clinical features consistent with peritonitis (abdominal pain and/or cloudy dialysate effluent); (2) the patient's dialysate effluent has a whole blood count (WBC) >100 cells/μL or >0.1 × 10/L with polymorphonuclear (PMN) cells >50 percent; and (3) positive dialysis effluent culture is identified.[98] Additionally, the guidelines recommend that PD patients presenting with cloudy effluent be presumed to have peritonitis and treated as such until the diagnosis can be confirmed or excluded.[99] Per the guidelines, this means that for patients undergoing PD treatments at home, it is recommended that they self-monitor for symptoms of peritonitis, cloudy dialysate and/or abdominal pain, and seek medical attention for additional testing and treatment upon experiencing any or both of these symptoms. According to the applicant, despite the fact that peritonitis is highly prevalent, symptom monitoring is insensitive and non-specific, which can contribute to late presentation for medical attention and treatment. The applicant asserted that under the current standard of care, PD patients face the following challenges in detecting peritonitis. First, the applicant stated that patients' fluid observation has low compliance rates as it relies on patients' close examination of their own dialysate effluent during PD treatments, which often occur while patients are asleep. Second, the applicant noted that it can be difficult for patients to visually detect peritonitis in dialysate effluent using a ''newspaper test'' for cloudiness, and can be even more difficult to see when the fluid is drained into a toilet, where it is diluted by water. The applicant stated that, as a result of these challenges, patients with ESRD suffer unsatisfactorily high mortality and morbidity from

[91] 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.

[92] 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.

[93] Mayo Clinic Staff, ''Peritonitis,'' June 18, 2020, available at: *https://www.mayoclinic.org/diseases-conditions/peritonitis/symptoms-causes/syc-20376247*.

[94] *Ibid*.

[95] *Ibid*.

[96] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078*.

[97] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[98] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078*.

[99] *Ibid*.

peritonitis, as well as high rates of PD modality loss, meaning they must discontinue PD and begin a different type of dialysis treatment. Per the applicant, the CloudCath System addresses these challenges by detecting changes in dialysate effluent at much lower levels of particle concentrations than the amount needed to accumulate for visual detection by patients.

Per the applicant, the CloudCath System consists of three components: (1) Drain set, (2) sensor, and (3) patient monitoring software. As explained in the application, the CloudCath System's drain set connects to a compatible PD cycler's drain line to enable draining and monitoring of dialysate effluent before routing the fluid to the drainage receptacle. Per the CloudCath System User Guide, included in the application, the CloudCath System is compatible with the following PD cyclers: Baxter Healthcare Home Choice PRO™, Baxter Healthcare AMIA™ Automated PD System, and Fresenius Liberty® Select Cycler. Per the applicant, once the CloudCath System is attached to a compatible cycler, the dialysate effluent runs through the drain set, through the CloudCath System's optical sensor. The applicant explained that the CloudCath System's optical sensor detects and monitors changing concentrations of solid particles in the dialysate effluent during each dialysis cycle and reports the concentrations in a turbidity score. Per the applicant, the CloudCath System will indicate whether dialysate effluent has normal turbidity and will notify the patient and/or health care professional if the dialysate effluent turbidity has exceeded the notification threshold set by the patient's dialysis provider. The applicant stated that the optical sensor's hardware and software components allow for data trending over time and remote monitoring by a healthcare professional.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, monitoring for peritonitis is a service that is essential for dialysis, and therefore would be considered a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that it is seeking 510(k) marketing authorization from the FDA. To be eligible for the TPNIES, the applicant must apply within three years of the FDA marketing authorization date and receive FDA marketing authorization by the HCPCS Level II deadline of July 6, 2021. The applicant stated that it anticipates the CloudCath System will receive FDA marketing authorization by the HCPCS Level II deadline.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the CloudCath System is not currently commercially available because it has not received FDA marketing authorization. The applicant noted that it expects the CloudCath System will be commercially available immediately after receiving FDA marketing authorization.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 6, 2021, the applicant stated that it has not submitted an application yet, but intends to apply by the deadline.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) SCI Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the SCI criteria specified in § 412.87(b)(1), the applicant asserted that the CloudCath System offers SCI over technologies currently available for the Medicare patient population by offering the ability to monitor changes in turbidity of peritoneal dialysate effluent through continuous remote monitoring in patients with ESRD receiving PD therapy, earlier than the current standard of care. By allowing the clinical standard of care to be initiated earlier, per the applicant, the use of the CloudCath System changes the management of peritonitis patients by enabling clinicians to both diagnose peritonitis and initiate antibiotic treatment earlier.

The applicant submitted two studies on the technology in support of the SCI claims. The applicant included a preliminary, unpublished report by Briggs, et al. on a clinical study that tested the ability of the CloudCath System and its dialysate effluent monitoring algorithm to detect indicators of peritonitis.[100] The proof of principle observational study consisted of 70 PD patients outside of the U.S. who had been on PD for a long interval of time (>10 days), and thus were at an increased risk of developing peritonitis. Out of the 64 PD patients whose data were included in the study, over 40 PD patients were receiving intermittent PD, which is not commonly used in the U.S. The remainder of the participants were receiving Continuous Ambulatory Peritoneal Dialysis. The report states that in the U.S., PD is generally performed in a modality called Continuous Cycling Peritoneal Dialysis (CCPD), in which a cycler automatically administers multiple dialysis exchange cycles, typically while patients sleep. Samples were collected from patients' PD effluent drainage bags and measured in the CloudCath System against a proprietary Turbidity Score threshold value and also tested for reference laboratory measurements according to ISPD guidelines for WBC count and differential (>100 cells/μL, >50 percent PMN).[101] Regarding the Turbidity Score threshold value, the study set a score to determine if the effluent sample in the CloudCath System was infected or not; samples greater than or equal to the Turbidity Score threshold value would be classified as infected, and samples less than the Turbidity Score threshold value would be classified as non-infected. The crude sensitivity and specificity of the CloudCath System was 96.2 percent and 91.2 percent, respectively. A majority of false positives (44 of 77 samples) occurred among patients already receiving antibiotic treatment for peritonitis, and another 20 false positive reports occurred because the patient had elevated turbidity due to a cause other than peritonitis. The investigators subsequently removed samples from patients already receiving treatment for peritonitis, setting the sensitivity for detecting peritonitis using the CloudCath System at 99 percent and the specificity at 97.6 percent.

The second study the applicant submitted is the Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis

[100] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[101] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH).[102] CloudCath initiated this ongoing single-arm, open-label, multi-center study to demonstrate that the CloudCath System is able to detect changes in turbidity associated with peritonitis in PD patients prior to laboratory diagnosis of peritonitis with a high degree of specificity and sensitivity. The target enrollment is 186 participants over 18 years of age using CCPD as their PD modality, with at least 2 exchanges per night.[103] Patients with active infection and/or cancer are excluded from the trial.[104] The primary endpoint is time of peritonitis detection by the CloudCath System (defined as two consecutive Turbidity Scores >7.0) as compared to laboratory evidence of peritonitis (defined as WBC count >100 cells/μL or >0.1 × 109/L with percentage of PMN >50 percent).[105] While the study is ongoing, the applicant included the study protocol and preliminary results with its application.[106] The preliminary results demonstrate that as of December 29, 2020, 132 participants have been enrolled in the CATCH Study at 13 sites.[107] Of the 132 enrolled participants, 59.1 percent of participants were male, 65.9 percent of participants were White and 29.6 percent of participants were Black or African American.[108] Enrolled participants underwent an average of 4.5 exchanges per night.[109] The preliminary results indicate that, as of December 29, 2020, there have been 7 peritonitis events that met the ISPD peritoneal fluid cell counts and differentials standard.[110] All 7 of the peritonitis events were also detected by the CloudCath System.[111] In 5 out of the 7 peritonitis events, the CloudCath System detected peritonitis 44 to 368 hours prior to the time of detection from a clinical laboratory.[112] The CloudCath System also detected peritonitis 27 to 344 hours prior to participants presenting to the hospital or clinic with signs or symptoms of peritonitis.[113] The applicant stated that these results support the claim that the CloudCath System would enable diagnosis of peritonitis earlier than the current standard of care through turbidity monitoring.

In addition to the studies on the technology, the applicant submitted an article by Muthucumarana, et al. on the impact of time-to-treatment on clinical outcomes of PD-related peritonitis.[114] The article includes data from the Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis (PROMPT) Study, a prospective multicenter from 2012 to 2014 that observed symptom-to-contact time, contact-to-treatment time, defined as the time from health care presentation to initial antibiotic, and symptom-to-treatment time in Australian PD patients. 116 patients participated in the survey, 83 of which were caucasian and 14 were aboriginal.[115] Out of the sample size of 116 survey participants, there were 159 episodes of PD-related peritonitis. Of these, 38 patient episodes met the primary outcome of PD failure (defined as catheter removal or death) at 30 days.[116] The median symptom-to-treatment time was 9.0 hours in all patients, 13.6 hours in the PD-fail group, and 8.0 hours in the PD-cure group.[117] The study found that the risk of PD-failure increased by 5.5 percent for each hour of delay of administration of antibiotics once patients presented to a health care provider.[118] However, neither symptom-to-contact nor symptom-to-treatment was associated with PD-failure in non-adjusted analyses, and the time from presentation to a health care provider to treatment was only associated with PD-failure outcomes in multivariable-adjusted analyses in a subset of patients who presented to hospital-based facilities. In addition to the Muthucumarana et al. article, the applicant cited to other studies that have found that antibiotic treatment should begin as soon as possible in order to effectively treat infections other than peritonitis.[119] [120] [121] Per the applicant, these articles on time-to-treatment demonstrate that the CloudCath System's ability to detect effluent changes substantially earlier improves the standard of care, enabling PD-related peritonitis diagnosis and antibiotic treatment earlier while decreasing the likelihood of PD-failure due to PD-related peritonitis.

The applicant also submitted letters of support from a nephrologist at an academic institution and the following ESRD patient advocacy groups: The American Kidney Fund, the American Association of Kidney Patients, and the International Society of Nephrology. The letter of support from Dr. Thomas A. Golper, president-elect of the International Society of Nephrology, endorsed the CloudCath System's ability to detect peritonitis and enable clinicians to begin to treat the infection earlier, preventing hospitalizations and related complications such as the abandonment of home dialysis. The letter also stated that the CloudCath System helps address the challenge of peritonitis as the main reason for abandonment of PD for HD, and will encourage a greater number of patients to select PD as their dialysis modality of choice. The letters from the American Association of Kidney Patients and the International Society of Nephrology encouraged CMS to consider the CloudCath System's application, explaining that the technology would have several benefits to patients, for example, by reducing peritonitis-related hospitalizations, increasing adherence to PD, and encouraging higher utilization of PD as a viable alternative to in-center HD. The American Kidney Fund's letter emphasized that peritonitis is a significant concern for PD patients [122] and requested CMS support of all efforts that ensure patients

[102] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[103] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Study Protocol (CC–P–001), June 24, 2020.

[104] *Ibid.*

[105] *Ibid.*

[106] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[107] *Ibid.*

[108] *Ibid.*

[109] *Ibid.*

[110] *Ibid.*

[111] *Ibid.*

[112] *Ibid.*

[113] *Ibid.*

[114] Muthucumarana, et al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[115] *Ibid.*

[116] *Ibid.*

[117] *Ibid.*

[118] *Ibid.*

[119] Gacouin, A. et al., ''Severe pneumonia due to Legionella pneumophila: prognostic factors, impact of delayed appropriate antimicrobial therapy,'' Intensive Care Medicine 28, 686–691 (2002), *https://doi.org/10.1007/s00134–002–1304–8.*

[120] Houck, PM. et al., ''Timing of antibiotic administration and outcomes for Medicare patients hospitalized with community-acquired pneumonia,'' Arch Intern Med. 2004 Mar 22;164(6):637–44. doi: 10.1001/archinte.164.6.637. PMID: 15037492.

[121] Lodise TP, et al., ''Outcomes analysis of delayed antibiotic treatment for hospital-acquired Staphylococcus aureus bacteremia,''Clin Infect Dis. 2003 Jun 1;36(11):1418–23. doi: 10.1086/375057. Epub 2003 May 20. PMID: 12766837.

[122] Mehrotra, Rajnish et al., ''The Current State of Peritoneal Dialysis,'' Journal of the American Society of Nephrology 27: 3238–3252, 2016. doi: 10.1681/ASN.2016010112, available at: *https://jasn.asnjournals.org/content/jnephrol/27/11/3238.full.pdf?with-ds=yes.*

with ESRD undergoing PD treatments can quickly detect and treat infections.

(b) CMS Preliminary Assessment of SCI Claims and Sources

After a review of the information provided by the applicant, we note the following concerns with regard to the SCI criterion under § 413.236(b)(5) and § 412.87(b)(1). We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether the CloudCath System meets the SCI criterion and other eligibility criteria for the TPNIES in the CY 2022 ESRD PPS final rule.

Because the applicant claims to offer the ability to diagnose a medical condition, PD-related peritonitis, earlier in a patient population than allowed by currently available methods, the applicant must also include evidence that use of the new technology to make a diagnosis affects the management of the patient, as required under the SCI criterion at § 412.87(b)(1)(ii)(B). Specifically, § 412.87(b)(1)(ii)(B) states that a determination that a technology represents SCI over existing technology means: The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

It is not clear to us whether the studies submitted demonstrate or examine the impacts of using the technology on patients with ESRD such that we can determine whether it represents an advance that substantially improves the treatment of Medicare beneficiaries compared to renal dialysis services previously available. We note that the studies submitted serve as ''proof of concept,'' as they provide evidence that the CloudCath System detects solid particles in dialysate effluent that may indicate PD-related peritonitis, and, may do so earlier than patient observation and a cell count test. However, the studies are limited in that they do not observe how the CloudCath System, in detecting the solid particles in dialysate effluent and doing so earlier than a cell count test, affects the management of the patient, as required under the SCI criterion at § 412.87(b)(1)(ii)(B). For example, as part of the CATCH Study, investigators deactivated the notification capability of the CloudCath System for the duration of the study, so that neither the participants nor the investigators would be aware of the device measurements.[123] Therefore, the CATCH study did not examine patient and clinician behavior, including the medical management of the patient, after the CloudCath System detected the solid particles in the dialysate effluent. The Briggs et al. study also did not examine how use of the CloudCath System impacted management of the patient. The investigators in that study stated, ''none of the data from our device was used for clinical decision making,'' meaning that the study did not test how or if the CloudCath System offered the ability to diagnose a medical condition and how use of the CloudCath System to make a diagnosis affected the management of the patient.[124] Because the studies submitted did not observe how patients and clinicians use the CloudCath System's monitoring to make decisions regarding patient management, we are concerned that we will not be able to make a determination on whether early detection of PD-related peritonitis by the CloudCath System meets the SCI criterion at § 412.87(b)(1)(ii)(B). Similarly, while the applicant submitted evidence to show that time-to-treatment plays a role in preventing PD failure in patients with ESRD with PD-related peritonitis,[125] CMS has not received any information regarding how the CloudCath System would affect management of the patient by reducing time-to-treatment for patients with ESRD receiving PD therapy. CMS also notes that the applicant referenced studies that support beginning antibacterial therapy for infections other than PD-related peritonitis, like pneumonia, and, therefore do not directly demonstrate the importance of time-to-treatment for PD-related peritonitis.

Additionally, it is not clear to us whether the CloudCath System would affect medical management of the patient because use of the technology may potentially detect solid particles in dialysate effluent so early, that, in some cases, healthcare providers may decide to wait for confirmation via patient symptoms, cell count, or positive culture as stated in the ISPD guidelines on diagnosis.[126] The preliminary results of the CATCH study demonstrate that in 5 out of 7 PD-related peritonitis events, the CloudCath System detected PD-related peritonitis 33 to 367 hours prior to the time of detection from a clinical laboratory.[127] The CloudCath System also detected PD-related peritonitis 27 to 344 hours prior to participants presenting to a healthcare facility with symptoms of PD-related peritonitis.[128] We note that no evidence was submitted to show that clinicians would begin to treat suspected peritonitis if the CloudCath System alerted the patient and clinician of possible PD-related peritonitis that was too early to detect via any of the ISPD guidelines.[129] In other words, we have not received evidence to demonstrate that the CloudCath System would affect medical management of the patient by replacing one of the ISPD guidelines for diagnosis.[130]

Additionally, CMS notes that the applicant has not submitted evidence to show that beginning treatment for presumed PD-related peritonitis in patients with ESRD prior to the occurrence of any of the ISPD guidelines would not be harmful to patients. In the Briggs et al. study, the CloudCath System identified 20 false positives that occurred because the patient had elevated turbidity due to some cause other than PD-related peritonitis.[131] However, the applicant did not explain or provide evidence on whether beginning treatment for PD-related peritonitis for a group of patients with ESRD who tested positive, but were in fact negative for the condition, was clinically advisable. CMS is concerned that the CloudCath System's potential for false positive results may lead to

[123] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report, NCT04515498, Jan 27, 2020.

[124] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[125] Muthucumarana, et al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[126] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[127] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[128] *Ibid.*

[129] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[130] *Ibid.*

[131] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

clinicians beginning treatment for PD-related peritonitis when not necessary in an already vulnerable group of Medicare beneficiaries. We welcome public comment on these issues.

(6) Capital Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant stated that the CloudCath System is not a capital-related asset. The applicant explained that the CloudCath System does not meet the definition of a capital-related asset, as defined in the Provider Reimbursement Manual (chapter 1, section 104.1), because the device is not subject to depreciation, nor is used by a provider as part of a regular lease agreement.[132]

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 in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Proposed Annual Payment Rate Update for CY 2022

1. CY 2022 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual productivity-adjusted market basket payment update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this proposed rule, the CY 2022 proposed ESRD PPS base rate is $255.55, which reflects the application of the proposed CY 2022 wage index budget-neutrality adjustment factor of .999546 and the CY 2022 proposed ESRDB market basket increase of 1.6 percent reduced by the productivity adjustment of 0.6 percentage point, that is, 1.0 percent. Accordingly, we are proposing a CY 2022 per treatment payment rate of $255.55 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index, as discussed in the next section of this proposed rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 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.[133] Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated previously, we are proposing a CY 2022 AKI dialysis payment rate of $255.55, adjusted by the ESRD facility's wage index.

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.

[132] CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*.

[133] Section 1881(b)(14)(D)(iv)(II) of the Act.

B. Extraordinary Circumstances Exception (ECE) Previously Granted for the ESRD QIP and 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.[134] 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 VBP program.[135] 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. We will respond to the public comments we received in the CY 2022 ESRD PPS final rule.

2. Notification of ECE Due to ESRD Quality Reporting System (EQRS) Issues

On November 9, 2020,[136] 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 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*.

Since the launch of EQRS, several critical data submission issues have 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.[137] Based on our assessment, the data submission issues only impact ESRD QIP, Dialysis Star Ratings, Dialysis Facility Compare and data submitted for ESRD Network quality improvement activities. We have analyzed the data submission issues and believe that the data systems issues will be resolved on or about July 12, 2021.

We recognize that these operational systems issues will prevent facilities from submitting ESRD QIP clinical data until the data systems issues are resolved. Therefore, we are announcing a blanket extension of remaining CY 2020 clinical reporting deadlines. Under this extension, facilities will have until September 1, 2021 to submit September through December 2020 ESRD QIP clinical data. We believe this reporting extension aligns with the time estimated for resolution of our operational systems issues and will give dialysis facilities nearly seven weeks to submit their data to EQRS. We will provide further details to facilities when the EQRS issues are resolved, as well as when facilities can begin submitting their data for CY 2020 and CY 2021, through routine communication channels to facilities, vendors, Quality Improvement Organizations (QIOs) and ESRD Networks. The communications could include memos, emails, and notices on the public QualityNet website (*https://www.qualitynet.org/*). We discuss the treatment of impacted CY 2020 data in this proposed rule. As this situation is ongoing, we will announce any relevant extension deadlines and data submission requirements for impacted CY 2021 data through the routine communication channels discussed above.

Because the current data submissions issue will not be resolved until on or about July 12, 2021 and has impacted all facilities that participate in ESRD QIP, we believe that granting a blanket ECE

[134] 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*.

[135] 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*.

[136] *https://mycrownweb.org/2020/11/november-2020-newsletter/*.

[137] *https://mycrownweb.org/2021/02/eqrs-data-reporting-update-feb-2021/*.

to all facilities without a request under 42 CFR 413.178(d)(6)(ii) is the appropriate remedy under these circumstances. We also believe that requiring facilities to report the CY 2020 data impacted by this ECE by September 1, 2021 is reasonable. In our data suspension announcements, we noted that facilities are expected to continue to use EQRS to collect clinical data to complete tasks such as admit and discharge patients, complete CMS 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 Facillity 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. 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.

While we are working to resolve all known systems issues by on or about 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 will 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 are concerned that facilities may be unfairly penalized because the current systems issues may impact the quality of the data. The EQRS system issues have resulted in multiple or incorrect dates of patient admissions and/or discharges, as well as showing duplicate patient records. Facilities have also expressed concerns about their experience with EQRS issues, noting that there is no way for a facility to verify accuracy or completeness. They have reported issues including missing record status in response files, which means that facilities do not know if the records were accepted or received an error response, and issues with determining whether clinical data are accepted because the information does not show in the user interface or the reports that facilities are receiving from EQRS.

We recognize stakeholders' concerns about the potential impact to the quality of data for CY 2020. We believe 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 are 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 proposed rule, we are proposing 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.

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 are 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.[138]

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 want 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 will need time to validate the impacted data after facilities are able to resume data submission. Due to the timing of this reporting extension, we believe that there are no feasible alternative data sources for PY 2022. Therefore, we believe that the scoring and payment modifications for PY 2022 as proposed in section IV.D in this proposed rule are appropriate in this situation.

C. Proposed Flexibilities for the ESRD QIP in Response to the COVID–19 PHE

1. Proposal To Adopt a Measure Suppression Policy for the Duration of the COVID–19 PHE

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 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 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.

It is not our intention to penalize dialysis facilities based on measure

[138] *https://www.cms.gov/files/document/cy-2021-final-technical-specifications-20201130.pdf.*

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 discussed above, 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 are also 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 are therefore proposing 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. We are also proposing, as described in more detail in section IV.C.2. of this proposed rule, 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 are proposing to adopt a special scoring and payment rule for PY 2022, as described more fully in section IV.D.

In developing this 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 believe 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 believe 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 believe 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 note 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 believe 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 are proposing to adopt these Measure Suppression Factors for use in the ESRD QIP and, for consistency, the following other VBP programs: Hospital VBP, 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 believe that these Measure Suppression Factors will help us evaluate measures in the ESRD QIP and that their adoption in the other VBP programs noted above will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are:

- *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.

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 noted above, 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 protect providers and suppliers from having their quality data used for quality scoring purposes while those data are likely to have been affected significantly by the COVID–19 PHE. However, this option would make quality data collection and reporting to CMS no longer mandatory and would leave no comprehensive data available for us 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, 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.

We view 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 intend 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 welcome 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.

2. Proposals To Suppress Four ESRD QIP Measures for PY 2022

a. Background

In response to the PHE for the COVID–19 pandemic, we have conducted analyses of the fourteen current ESRD QIP measures to determine whether and how COVID–19 may have impacted the validity of these measures. For the reasons discussed below, we have concluded that COVID–19 has so severely impacted the validity of four measures that we cannot fairly and equitably score these measures for the PY 2022 program year, and we are proposing to suppress these measures for the PY 2022 program year for all ESRD QIP participants. Specifically, the measures we are proposing to suppress for the PY 2022 ESRD QIP are as follows:

- SHR clinical measure (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; and proposed Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:
  ++ Healthcare personnel;
  ++ medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix);
- Standardized Readmission Ratio (SRR) clinical measure (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; and proposed 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 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); and
- Long-Term Catheter Rate clinical measure (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).

b. Proposal To Suppress the SHR Clinical Measure for PY 2022

We are proposing 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 are 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. 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 are concerned about the effects of the observed COVID–19 hospitalizations on the SHR clinical measure. We also note 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 are concerned that these regional differences in COVID–19 rates has led to distorted hospitalization rates such that we cannot reliably measure national performance on the SHR clinical measure.

Our analysis of the available Medicare claims data indicates that the COVID–19 PHE has had significant effects on hospital admissions of dialysis patients, and will 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 are concerned that similar effects will 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 are concerned 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 believe the resulting performance measurement on the SHR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP.

We are proposing 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 are concerned that the COVID–19 PHE affects 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 would continue to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2022 data where feasible and appropriately caveated.

We are 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 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 believe this approach might help distinguish between ESRD-related hospitalizations and COVID–19 related hospitalizations that might otherwise impact SHR clinical measure calculations.

We welcome public comment on our proposal to suppress the SHR clinical measure for PY 2022.

c. Proposal To Suppress the SRR Clinical Measure for PY 2022

We are proposing 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 has always been 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 are 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 indicates 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 are 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 meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believe the resulting performance measurement on the SRR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP.

We are proposing 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 are concerned that the PHE for the COVID–19 pandemic affects measure performance on the current SRR clinical measure such that we will not be able to score facilities fairly or equitably on it. Additionally, we would continue to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2022 data where feasible and appropriately caveated.

We are 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 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 believe this

approach might help distinguish between ESRD-related readmissions and COVID–19 related readmissions that might otherwise impact SRR clinical measure calculations.

We welcome public comment on our proposal to suppress the SRR clinical measure for PY 2022.

d. Proposal To Suppress the ICH CAHPS Clinical Measure for PY 2022

We are proposing 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 have 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.[139] 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), 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 indicates 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 believe 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. 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 believe the ICH CAHPS clinical measure meets the criteria for Measure Suppression Factor 1.

We also believe that this significant change in performance may unfairly penalize facilities and that suppressing this measure for the PY 2022 program year will 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 believe 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 are proposing 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. However, we are concerned that the COVID–19 PHE affects measure performance on the current ICH CAHPS measure such that we will 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 can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2022 data where feasible and appropriately caveated.

We welcome public comment on our proposal to suppress the ICH CAHPS measure for the PY 2022 program year.

e. Proposal To Suppress Long-Term Catheter Rate Clinical Measure for PY 2022

Under the measure suppression policy discussion in section IV.C.1 of this proposed rule, we are proposing 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 have 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 the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) and excludes patient-months where a patient has a catheter in place and has a limited life expectancy.

[139] Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/ICH_Composites_English.pdf.*

Our analysis based on the available data indicates that long-term catheter use rates have 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, 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. We are 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 are proposing 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 are concerned that the PHE for COVID–19 affects measure performance on the current Long-Term Catheter Rate clinical measure such that we will 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 can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2022 data where feasible and appropriately caveated.

We welcome public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for the PY 2022 program year.

D. Proposed Special Scoring Methodology and Payment Policy for the PY 2022 ESRD QIP

As described in section IV.B.2 of this 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. In addition, as described in section IV.C. we believe 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 are proposing 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 proposed above, we believe that four of them have additionally been significantly impacted by COVID. Because we would not calculate achievement and improvement scores for any measures, we are also proposing 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 are also proposing 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 are proposing 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 propose to codify these policies for PY 2022 at 42 CFR 413.177(a) and § 413.178(h).

However if the policies in sections IV.C and IV.D of this proposed rule are not finalized, the PY 2022 ESRD QIP payment would be as 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 invite public comment on this proposed special scoring and payment policy for the PY 2022 ESRD QIP.

E. Proposed 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 are described in Table 2. 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.[140]

BILLING CODE 4120–01–P

[140] *https://www.cms.gov/files/document/esrd-measures-manual-v61.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.

BILLING CODE 4120–01–C

We discuss our proposal to update the SHR clinical measure in the following section.

a. Proposal To Update 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.

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.[141] Hospitalizations account for approximately 33 percent of total Medicare expenditures for ESRD patients.[142] Studies have shown that improved health care delivery and care coordination may help reduce unplanned acute care including hospitalization.[143] 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.[144] 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.[145] In its final report, the Measure Applications Partnership supported this measure for rulemaking.[146]

In this proposed rule, we are proposing to update the SHR clinical measure specifications to align with the NQF-endorsed updates. These include 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.

We believe 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 believe that these updates would result in a more reliable and robust SHR clinical measure.

We seek comment on this proposal to update the SHR clinical measure specifications for use in the ESRD QIP beginning with PY 2024.

[141] 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.

[142] *Ibid.*

[143] 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.*

[144] 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.

[145] 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.*

[146] 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.*

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. Proposal To Update 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 response to the COVID–19 PHE, first and second quarter data for CY 2020 are excluded from scoring for purposes of the ESRD QIP. We are concerned that it will be difficult to assess levels of achievement and improvement if the performance standards are based on partial year data.[147] Our preliminary analysis indicates 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 adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years. 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. We are 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.

Therefore, in this proposed rule, we are proposing to calculate the performance standards for PY 2024 using CY 2019 data, which is 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 is excluded from the ESRD QIP for scoring purposes, we believe 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 welcome public comments on this proposal.

b. Performance Standards for the PY 2024 ESRD QIP if Proposal to Use CY 2019 as the Baseline Period is Finalized

Table 3 displays the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2024 clinical measures, and we would use these standards if our proposal to use CY 2019 as the baseline period is finalized.

BILLING CODE 4120–01–P

[147] We note that for most ESRD QIP measures, this partial year data would be measure data from July and August 2020.

TABLE 3: Performance Standards for the PY 2024 ESRD QIP Clinical Measures if Proposal to Use CY 2019 as the Baseline Period is Finalized

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 have summarized in Table 4 existing requirements for successful reporting on reporting measures in the PY 2024 ESRD QIP. We are not making 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 proposed rule is based on data from CY 2019 instead of the PY 2024 baseline period (CY 2020) because we have proposed to use CY 2019 as the baseline period for that payment year.

We refer readers to Table 3 for the estimated values of the 50th percentile of national performance for each clinical measure. Under our current policy, a facility that achieves a TPS of 56 or below would receive a payment reduction based on the TPS ranges indicated in Table 6.

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%

BILLING CODE 4120–01–C

If we do not finalize the proposed update to our performance standards policy as described in section IV.E.2.a of this proposed rule, 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.

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. At this time, we are not proposing 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.

In this proposed rule, we are not proposing 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 proposed rule, we note that we are proposing 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). 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).

In this proposed rule, we are not proposing 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).

In this proposed rule, we are not proposing any changes to this policy 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 are not proposing 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, we request 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. The following 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, request for information (RFI) focused on closing the health equity gap in CMS programs and policies. This RFI contains four parts:

- *Background.* This section provides 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 describes the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results.* This section describes 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 specifies 11 requests for feedback on the topics specified in this RFI.

a. Background

Significant and persistent inequities in health care outcomes exist in the U.S.[148] 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.[149 150 151 152 153 154 155 156] 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.[157 158 159 160 161 162] 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.[163 164 165 166 167] Although Black Americans represent 7.5 percent of all older adult Medicare beneficiaries, they represent 28 percent of those with ESRD.[168] Among individuals with ESRD the odds of 30-day hospital readmission are 19 percent higher for Black beneficiaries as compared with white beneficiaries.[169] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[170] 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

[148] 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.*

[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] 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.

[151] 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.

[152] 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.

[153] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[154] 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.

[155] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[156] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7386532/.*

[157] 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.

[158] 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.*

[159] 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.

[160] 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.

[161] 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.

[162] 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.

[163] 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.

[164] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[165] 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.*

[166] 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.

[167] 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.

[168] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.*

[169] *Ibid.*

[170] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

persons relative to white persons.[171] [172] 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.[173] As noted by the Centers for Disease Control ''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.'' [174] 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.[175] 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.'' [176] 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.[177] 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.[178] The CMS Quality Strategy [179] and Meaningful Measures Framework [180] 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.[181]
- 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.[182]
- The *Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[183]
- 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.[184]
- 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 may improve care and suggests other available resources that may be used by primary care practice teams in caring for vulnerable patients.[185]
- *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission

[171] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[172] 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/.*

[173] 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.

[174] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[175] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[176] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[177] Centers for Medicare and 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.*

[178] Centers for Medicare and 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.*

[179] Centers for Medicare Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[180] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[181] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[182] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[183] 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.*

[184] 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.*

[185] 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.*

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) [186] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [187] which have examined the influence of social risk factors on several of our quality programs. In this request for public comment, we address 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 discuss the implementation of these methods to date and present considerations for continuing to improve and expand these methods.

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).[188] 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.[189] 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 are seeking 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 above, landmark reports by NASEM [190] and ASPE,[191] 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 the Within-Facility and Across-Facility methods. The first method (based on the Within-Hospital disparity method, described above) 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 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

[186] 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.*

[187] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[188] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[189] Centers for Medicare Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[190] 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.*

[191] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

complications.[192] We also note that the prevalence of ESRD is higher among racial minorities.[193] 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.[194] 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.[195] 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.[196] Another example, the ''Race & Ethnicity—CDC'' code system in Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS)[197] 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. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.[198] 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.[199] In recent decades, to address these data quality issues, CMS has undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive race and ethnic identification.[200] [201] 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.[202] 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[203] 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.[204]

The Office of the National Coordinator for Health Information Technology (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 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.[205]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize

[192] *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[193] 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.*

[194] 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.*

[195] 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.

[196] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[197] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

[198] ONC criteria for certified health IT products: *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity.*

[199] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[200] 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.

[201] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[202] Centers for Medicare and 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.*

[203] Centers for Medicare and 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.*

[204] *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.

[205] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

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.[206] 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.[207]

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).[208] 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.[209]

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.[210] Validation testing reveals concordances of 0.88–0.95 between indirectly estimated and self-report among individuals who identify as White, Black, Hispanic, and Asian Pacific Islander for the MBISG version 2.0 and concordances with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1.[211] [212] 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.[213]

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 feel 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 are interested in learning more about, and soliciting 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 and ethnicity 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.[214] Collection and 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

[206] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[207] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[208] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[209] 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.

[210] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[211] 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.

[212] *https://www.cms.gov/files/document/racial-ethnic-gender-disparities-health-care-medicare-advantage.pdf.*

[213] 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.

[214] The 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.*

exchange, can significantly enhance the accuracy and robustness of our equity reporting.[215] 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 are soliciting 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)[216] and standards for interoperable exchange (such as the U.S. Core Data for Interoperability put forth by the Office of the National Coordinator for Health Information Technology for incorporation in certified health IT products as part of the 2015 Edition of health IT certification criteria.)[217] 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 above, 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.[218]

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 QIN–QIOs 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 are seeking comment on the possibility of stratifying ESRD QIP measures by dual eligibility and race and ethnicity. We are soliciting public comments on the application of the within-facility or across-facility disparities methods if we were to stratify ESRD QIP measures. We are also seeking 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 are seeking 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 look forward to receiving feedback on these topics and note for readers that responses to the RFI will not directly impact payment decisions. We also note our intention for additional RFI or rulemaking on this topic in the future.

Specifically, we are inviting public comment on the following:

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

[215] 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.*

[216] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[217] *https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf.*

[218] Agniel D., Martino S.C., 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.

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.

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.

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.

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).[219] COVID–19 is a contagious respiratory infection [220] 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.[221]

As of April 2, 2021, the U.S. reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[222] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[223] From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[224]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[225] 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.[226] 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.[227] 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.[228] Another means of less common transmission is contact with a contaminated surface.[229] 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.[230] 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.[231] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[232]

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.[233] After achieving this goal,[234] the Biden Administration announced a new goal to administer at least one COVID–

[219] 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.*

[220] 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.*

[221] *Ibid.*

[222] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[223] 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.*

[224] U.S. Currently Hospitalized | The COVID Tracking Project. *Accessed January 31, 2021 at: https://covidtracking.com/data/charts/us-currently-hospitalized.*

[225] 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.*

[226] *Ibid.*

[227] *Ibid.*

[228] *Ibid.*

[229] *Ibid.*

[230] 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.*

[231] 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.*

[232] 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.

[233] 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/.*

[234] 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/.*

19 vaccine shot to 70 percent of the U.S. adult population by July 4th, 2021.[235] 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.[236] 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.[237] Research suggests most states followed this recommendation,[238] and HCP began receiving the vaccine in mid-December of 2020.[239] 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,[240] ACIP recommendations indicated that ESRD patients would be offered the COVID–19 vaccine based on their high-risk status as part of phase 1c.[241]

As of June 22, 2021 the CDC reported that over 319 million doses of COVID–19 vaccine had been administered, and approximately 150.4 million people had received a complete vaccination course.[242] 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.[243] 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.[244]

b. COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

We believe 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 continue serving their communities throughout the PHE and beyond. We recognize the importance of COVID–19 vaccination, and have proposed to include a COVID–19 HCP vaccination measure quality measure in various pay for reporting programs, such as the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 19501 through 19504), the Hospital Inpatient Quality Reporting Program (86 FR 25571 through 25575), and the Skilled Nursing Facility Quality Reporting Program (86 FR 19994 through 19998). We note that there is not a pay for reporting program under the ESRD PPS, however, we believe 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[245] and another for patient COVID–19 vaccination[246] 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,[247] and were able to begin weekly COVID–19 vaccination reporting for patients in March 2021.[248] Currently, 89 percent of ESRD facilities are reporting HCP vaccination rates and almost 95 percent of ESRD facilities are reporting patient vaccination rates on these measures. We are 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 are also exploring the potential future inclusion of a COVID–19 vaccination measure to the ESRD QIP. Therefore, we are seeking 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. We believe 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.[249] Data from influenza vaccination

[235] 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/*.

[236] 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*.

[237] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. 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.

[238] 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/*.

[239] Associated Press. 'Healing is Coming:' U.S. Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[240] 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/*.

[241] 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.

[242] 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*.

[243] 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/*.

[244] 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/*.

[245] *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html*.

[246] *https://www.cdc.gov/nhsn/dialysis/pt-covid-vac/index.html*.

[247] *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-guidance-508.pdf*.

[248] *https://www.cdc.gov/nhsn/pdfs/dialysis/covidvax/getting-started-508.pdf*.

[249] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health

Continued

demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[250] and we believe HCP COVID–19 vaccination in dialysis facilities could similarly increase uptake among that patient population. We also believe that publishing the HCP vaccination rates will 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

We believe 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.[251] Many patients treated in ESRD facilities have other underlying chronic conditions, and therefore are highly susceptible to illness and disease.[252] Sufficient vaccination coverage among patients in ESRD facilities may reduce transmission of SARS–CoV–2, thereby protecting them from COVID–19 mortality. Therefore, we are seeking 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.

We believe 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 believe that publishing the vaccination rates will 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.[253] 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 providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[254] 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.[255]

In its preliminary recommendations, the Measure Applications Partnership Hospital Workgroup did not support these two measures for rulemaking, subject to potential for mitigation.[256] 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.[257] 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.[258] The Measure Applications Partnership specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [259] 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.[260] 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 this proposed rule, we would like to seek 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.[261]

We are also interested in public comment on data collection,

Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[250] 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.*

[251] 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.*

[252] *Ibid.*

[253] 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.

[254] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[255] *Ibid.*

[256] *Ibid.*

[257] *Ibid.*

[258] 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.*

[259] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[260] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[261] Specifications for both measures available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.*

submission, and reporting for the COVID–19 vaccination measure for HCP and the COVID–19 vaccination measure for patients. For example, we are 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 seek 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 anticipate rulemaking on this requirement in the CY 2023 rulemaking cycle.

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 are issuing this request for information (RFI). The purpose of this RFI is 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 contains four parts:

- *Background.* This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides 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 provides 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 introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- *Solicitation of Comments.* This part lists 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).[262] 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).[263] 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.[264] 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

[262] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[263] 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.*

[264] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

Certification Program until December 31, 2022 (85 FR 70064).[265]

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.[266] 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 this section we seek 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 seek 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 note 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 proposed rule. In this section, we are seeking comment on the potential definition of dQMs in this RFI.

We also seek 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.[267] These fully digital measures continue to be important drivers of interoperability advancement and learning. CMS is 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. CMS intends 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

[265] 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.*

[266] 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://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

[267] eCQI Resource Center, *https://ecqi.healthit.gov/.*

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 are requesting 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 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 are seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We are also seeking feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcome 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 seek 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 are 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 [268] 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 seek feedback on aggregation of data from multiple sources being used to inform measurement. We also seek 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.[269] 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 seek 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 seek 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

As noted previously, we seek input on the future development of the following:

• *Definition of Digital Quality Measures:* We are seeking 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

[268] 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.*

[269] 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.*

also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

• Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025

++ We are seeking feedback on the following as described in section IV.G.3.c.(1) of this proposed 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 are seeking feedback on the following as described in section IV.G.3.c.(2) of this proposed rule:

—What functionalities, described in section IV.G.3.c.(2) of this proposed 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 seek feedback on the following as described in section IV.G.3.c.(3) of this proposed 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 seek feedback on the following as described in section IV.G.3.c.(4) of this proposed rule:

—What are initial priority areas for the dQM portfolio (for example, measurement areas, measure requirements, tools)?

—We also seek 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 plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will 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 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.

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 [270] 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

In this proposed rule, we are proposing 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 are proposing changes to the methodology

[270] ZIP code ™ is a trademark of the United States Postal Service.

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 are also proposing 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 an LDO as well as Managing Clinicians, to incentivize additional alternative renal replacement modalities. In addition, we are proposing 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 are proposing 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 are proposing to stratify PPA achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the Low-Income Subsidy 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 are proposing 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 are proposing to add processes and requirements for CMS to share certain model data with ETC Participants. We are also proposing additional programmatic waivers 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 propose to permit Managing Clinicians who are ETC Participants to reduce or waive beneficiary coinsurance for kidney disease patient education services, subject to certain requirements. CMS expects that the proposed changes would continue to 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.

3. Impact of Proposed 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).

We propose to update the evaluation plan presented in the Specialty Care Models final rule to account for all the policies proposed in this rule, if finalized. However, changes in the construction of the PPA, if finalized, 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 expect to 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 section IX.B.4 of this proposed 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), where 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). We clarify 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.

B. Provisions of the Proposed Rule

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 this proposed rule, we are clarifying the claims 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 specify 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). Since publication, 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.

2. Performance Payment Adjustment (PPA) Beneficiary Attribution for Living Kidney Donor Transplants

In the Specialty Care Models final rule, we established that beneficiaries are attributed to Managing Clinicians for the purposes of calculating the home

dialysis rate and transplant rate (85 FR 61297). 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).

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. 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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). CMS is proposing 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 seek 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).

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.[271]

[271] Wilk, Adam S., Lea, Janice P. (2019). How Extended Hemodialysis Treatment Time Can Affect

Continued

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.[272] [273] [274] [275] [276]

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 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.[277] [278]

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 section IX.B.4.a.(4) of this proposed 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.[279]

c. Proposed Inclusion of Nocturnal In-Center Dialysis in Home Dialysis Rate

We propose 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 previously in this section of the proposed 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, we believe 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, we believe 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.

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 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.[280] Other academic research

Patient Quality of Life. Clinical Journal of the American Society of Nephrology, 23, 479–485. doi:10.1111/hdi.12782.

[272] Burton, J. and Graham-Brown, M., 2018. Nocturnal hemodialysis. Current Opinion in Nephrology and Hypertension, 27(6), pp.472–477.

[273] 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.

[274] 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.

[275] 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.

[276] 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.

[277] 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.

[278] 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.

[279] *Ibid.*

[280] United States Renal Data System. 2015. ''2015 Researcher's Guide to the USRDS Database.''

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.[281] [282] 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.[283] Based on our review of definitions commonly used, for the purposes of the ETC Model we propose 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. Based on the current distribution of numbers of ESRD facilities owned by dialysis organizations operating in the market, we believe 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 believe 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 seek 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 acknowledge 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 propose 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 believe 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 propose 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 propose 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 seek comment on these proposed changes to § 512.365(b).

4. Performance Payment Adjustment 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.

https://usrds.org/media/2219/2015_usrds_researchers_guide_15.pdf.

[281] 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.

[282] 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.

[283] 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.*

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 do not believe that it would be appropriate to update the transplant rate to include accountability for deceased donor transplants, rather than transplant waitlisting, at this time. 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.

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, 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 propose 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 propose 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 are proposing 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 propose 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, 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 propose 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 seek 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.

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–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).

We continue 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. Based on our additional analysis of Medicare claims data show 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. Proposed Achievement Benchmarking and Scoring

(1) Achievement Benchmarking and Scoring for MY3 Through MY10

We propose 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. Rather than using rates observed in Comparison Geographic Areas, we propose 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 propose 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 CMS analyses detailed in section IX.B.4 of this proposed 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 (85 FR 61354). In section IX.B.4 of this proposed rule, updated projections assume the same projected growth rate, but note that observed rates of increase have accelerated in more recent data. As such, we believe that this proposed 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 note that, unlike in the Specialty Care Models proposed rule (84 FR 34556), we are 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

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 believe 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 believe 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.

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.

We believe that the proposed approach for increasing achievement benchmarks over the course of the ETC Model balances 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 section IX.B.4.a.(3) of this proposed rule). We also believe 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 seek 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.

(2) Achievement Benchmark Stratification by Dual-Eligible and Low Income Subsidy (LIS) Status

We also propose 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. 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 propose to determine whether an attributed beneficiary was dual-eligible or received the LIS for a given month using Medicare administrative data. We believe 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 expect that stratifying the achievement benchmarks as proposed would increase home dialysis rate and transplant rates for such ETC Participants.

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, 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 are proposing only two strata.

We seek 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.

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 section V.B.5.b of this proposed 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 previously in this section of the proposed rule, we are proposing 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, this 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. We are interested 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.

c. Proposed Changes to Improvement Benchmarking and Scoring

(1) Revised Improvement Calculation

As described above, 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 propose 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 propose 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. CMS does 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. 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.

(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 propose to add a Health Equity Incentive to the improvement scoring methodology. We propose 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 propose 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 previously in this section of the proposed 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. We believe 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. We believe 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 believe 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 believe this incentive to reduce socioeconomic disparities in access to alternative renal replacement modalities would be an improvement to the PPA scoring methodology.

We propose to amend § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology, beginning for MY3. We propose 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 propose 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. The Health Equity Incentive would allow ETC Participants to increase their improvement score, and thereby increase their payment adjustment.

We propose 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 believe 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. We anticipate improvement in home dialysis and transplant rates among dual-eligible or LIS recipients between the MY and the Benchmark Year, but 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 propose that an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to be dual eligible or an LIS recipient for a given month if at any point during the month the beneficiary was dually eligible for Medicare and Medicaid or an LIS recipient. We propose to determine whether an attributed beneficiary was dual-eligible or received the LIS using Medicare administrative data.

We propose 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 above, would be specified at § 512.370(c)(2). We seek comment on the proposal to modify § 512.370(c) accordingly.

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 believe that setting a threshold for earning the Health Equity Incentive applicable for all MYs, beginning for MY3, is more appropriate. 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 believe 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 propose that ETC Participants in aggregation groups that fall below a low-volume threshold would be ineligible to earn the Health Equity Incentive. Specifically, we propose 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 believe 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 are proposing 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 propose to amend the Modality Performance Score (MPS) methodology to incorporate the Health Equity Incentive. To that end, we propose 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 propose 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 seek 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 seek 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.

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 Participant have timely access to these ETC Model reports, we are proposing 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. 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, 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. 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. CMS additionally believes that timely access to this data is important and proposes 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 proposed rule, we describe our proposed process for CMS to share and for ETC Participants to retrieve certain beneficiary-identifiable attribution data and performance data, as well as the protections that would 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 propose 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 are proposing 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 propose 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 are proposing 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 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 during any communications with a beneficiary or a beneficiary's caregiver, as appropriate and allowable. In addition, 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 propose 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 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.

We recognize there are sensitivities surrounding the disclosure of individually-identifiable (beneficiary-specific) health information, and we note that a number of laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule provides that legal authority and authorizes this proposed disclosure of individually identifiable health information by us to ETC Participants. 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 individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule, without the individual's authorization. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI, without an individual's authorization. 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.

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.[284] We are proposing to establish a requirement under § 512.390(b)(1) for CMS to share this data with ETC Participants.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply, 5 U.S.C. 552a(b). ''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purposes for which the data discussed in this rule was collected, and thus, 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.

We believe that establishing a regulatory requirement for CMS to share the beneficiary-identifiable data described above would be appropriate for the ETC Model for several reasons. First, 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, CMS believes that all ETC Participants, regardless of size, would have the capability of managing and meaningfully using the shared data. 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, CMS believes that any other approach to making beneficiary-identifiable data available, including the alternative proposal considered by CMS and described below, 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.

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

[284] Under 45 CFR 164.103, ''Required by law'' means ''a mandate contained in law that compels 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.''

would have the opportunity to request the data for their own ''health care operations'' 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) and § 164.501. 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 the next section of this proposed rule.

After considering this option, we believe 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 further believe that adding these steps would not produce a meaningful privacy or security benefit based on the specific circumstances of this ETC Model. Both this option and the approach proposed above 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, there are no meaningful privacy or security benefits that this option would create that are not already realized by the proposed approach to data sharing in the ETC Model. We also anticipate that all ETC Participants would want and need, and overwhelmingly would request, the data described previously in this section, would be capable of handling such data, and would take the steps necessary to obtain the data. In addition, 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 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 proposed in this section and the following sections related to data sharing, we propose to modify the title of § 512.390 from ''Notification and targeted review'' to ''Notification, data sharing, and targeted review.'' We propose this change so that the section title will more accurately reflect the contents of the section.

We solicit 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.

(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, we are proposing 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 propose 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 Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations and agrees to comply with the terms of a separate data sharing agreement. Although we expect ETC Participants are covered entities and must comply with the HIPAA regulations directly, we are including 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. 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 propose 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. 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 discuss in more detail in later sections of this proposed rule. This agreement also potentially would require the ETC Participant to make certain attestations, for example, if required under the applicable Privacy Act system of records notice. 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. CMS believes 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 below, we propose 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.

CMS believes 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 previously in this section of the proposed rule, there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ETC Participants would be further protected in an appropriate fashion.

We considered an alternative proposal 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 an alternative proposal 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 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 solicit 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.

(2) Content of ETC Data Sharing Agreement Provisions for Beneficiary-Identifiable Data

We are proposing 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. CMS believes that 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. CMS believes that these proposals would allow CMS to accomplish that.

CMS seeks public comment on the additional privacy, security, breach notification, and other requirements that we would include in the ETC Data Sharing Agreement. CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA privacy, security and breach notification regulations. These provisions would not prohibit the ETC Participant from making any disclosure of the data otherwise required by law.

CMS is considering limiting the use of beneficiary-identifiable data for specific purposes, either alone or in combination. For example, in the ETC Data Sharing Agreement, CMS is considering 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 this section of the proposed 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. Importantly, there is no other source of this information outside of CMS. In addition to limiting use to reviewing how CMS calculated the ETC Participant's MPS, CMS is also 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. CMS believes 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, CMS is also 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 activates, 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, CMS believes 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 seek 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.

CMS also seeks 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, CMS is considering

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 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, CMS is also considering 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.

CMS is considering all of these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data discussed previously in this section of the 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. CMS believes 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. CMS also believes 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 seek 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 are considering 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. These are only examples, and are not the only terms CMS would potentially include in the ETC Data Sharing Agreement.

We solicit 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 above, CMS proposes, 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 propose 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 propose 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. This proposed change, if finalized, would align the regulatory provision on remedial action with the proposed remedial action we propose to include in the ETC Data Sharing Agreement.

We solicit 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.

(3) Process for Retrieving the ETC Data Sharing Agreement and Beneficiary-Identifiable Data

We propose that we would make the ETC Data Sharing Agreement and beneficiary-identifiable data available in a form and manner specified by CMS. We expect to provide a web-based platform for ETC Participants to use to retrieve the beneficiary-identifiable data. 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 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. 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 proposed rule. We propose that ETC Participants would be permitted to retrieve this data at any point during the relevant PPA Period. 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.

CMS believes 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. 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 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 solicit 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 solicit comment regarding our expectation that we will use a web based platform, rather than paper mail, for these purposes.

e. CMS Sharing of Aggregate Data

In addition to the proposed process for sharing beneficiary-identifiable data described previously in this section, we are proposing 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. 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. CMS believes that 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. Whereas the beneficiary-identifiable data described previously in this section of the proposed 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 are proposing 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 expect 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. 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 believe 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, 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 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 solicit 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 solicit 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.

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. Proposed 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.

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. 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 believe 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. 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. 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 believe that removing beneficiary cost barriers for kidney disease patient education services would be helpful. As we demonstrate below, 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 propose 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 propose 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 proposes to amend § 512.397 to add a waiver of certain telehealth requirements to provide qualified staff, as we are proposing to define for purposes of the ETC Model at § 512.310, the flexibility to furnish kidney disease patient education services via telehealth for the reasons described above. Specifically, we propose 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 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. CMS also proposes 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 do 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 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 propose that kidney disease patient education services could be furnished via telehealth health only by qualified staff. We used the term ''clinical staff'' and ''qualified staff'' in the Specialty Care Models final rule, but did not provide definitions of these terms. For clarity, we now propose to define ''clinical staff'' and ''qualified staff'' in 42 CFR 512.310. We propose 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 are proposing 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 propose 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 seek 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 seek 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.

(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.[285] 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.[286] In light of this research, CMS believes that cost represents a meaningful barrier for beneficiaries in accessing kidney disease patient education services. While 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 CY2021 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.

CMS believes 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 believe this patient incentive, if finalized, 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. CMS has 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, beginning January 1, 2022, we propose at § 512.397(c) to permit 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 certain conditions are satisfied. We refer to this patient incentive herein as the ''kidney disease patient education services coinsurance patient incentive.'' As more fully explained below, we expect 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

[285] 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).

[286] 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.*

Model requirements with respect to kidney disease patient education services. If CMS makes 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 are proposing 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. 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 below.

We are proposing to limit the kidney disease patient education services coinsurance patient incentive to beneficiaries who do not have secondary insurance, as secondary insurance typically provides cost-sharing support of the type CMS is proposing in this proposed rule. 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 are also proposing 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 are proposing to include this requirement because we waived some but not all provisions of § 410.48, and 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.

CMS proposes 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, we are considering limiting the kidney disease patient education services coinsurance patient incentive to kidney disease patient education services furnished to an individual beneficiary, rather than allowing the kidney disease patient education services coinsurance patient incentive for kidney disease patient education services furnished either individually or to a group. 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, 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 solicit comments on this issue.

An ETC Participant that offers coinsurance support for kidney disease patient education services would be required to maintain records of certain information. Specifically, 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 propose 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) of this part.

We further propose 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).

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 kidney disease patient education services coinsurance permitted under the ETC Model final rule, if issued. Specifically, 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 propose that, if we make this determination, we would specify in regulation text at § 512.397(c)(4) that the safe harbor is available.

We are also considering 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. 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 solicit comments on whether this prohibition is a 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. This is the authority under which we would waive

such Medicare payment requirements. 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, 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 policies proposed in this section related to programmatic waivers and additional flexibilities available under the ETC Model, we propose to modify the title of § 512.397 from ''ETC Model Medicare program waivers'' to ''ETC Model Medicare program waivers and additional flexibilities.'' We propose 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 solicit public comments on our proposal to allow qualified staff, as we propose 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 solicit 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.

(3) Revising Language Providing Other ETC Model Medicare Program Waivers

We propose to revise § 512.397(b)(1) through (4) in their entirety to accomplish a few goals. First, we propose 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 propose 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 is proposing to add definitions for ''clinical staff'' and ''qualified staff'' in this proposed rule, and CMS believes clarifying how CMS discusses these individuals in § 512.397(b) will enhance clarity. Finally, CMS is proposing 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. CMS believes that its inclusion of clinic/group practices previously was in error; a clinic/group practice is not able to furnish or bill for kidney disease patient education services under existing law and CMS did not intend for the waiver described in § 512.397(b) to permit anyone other than a clinican 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 are proposing to remove references to 42 CFR 410.48(c)(2)(i) in § 512.397(b)(1) of this part.

We solicit 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.

C. Requests for Information (RFIs) on Topics Relevant to the ETC Model

This section includes several requests for information (RFIs). In responding to the RFIs, the public is encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs will be solely at the respondent's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted.

Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual respondents. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Peritoneal Dialysis Catheter Placement

The most common modality of home dialysis is peritoneal dialysis (PD). In order to perform PD, a beneficiary needs placement of a PD catheter. A PD catheter is a flexible plastic tube that enables dialysate to enter the abdomen for blood filtration purposes. The catheter is generally installed via outpatient surgery, as it is an invasive procedure.

However, CMS has heard concerns from numerous stakeholders about their ability to effectively get PD catheters installed in beneficiaries who may be otherwise interested in home dialysis. These stakeholders reported a variety of issues related to PD catheter placement, including 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.[287] As many stakeholders have pointed out, the lack of timely PD catheter placement is a key barrier preventing many beneficiaries from being able to use PD as a dialysis modality.

Based on these issues, we seek feedback about how CMS can test and

[287] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2924406/#B38.*

use Medicare payment policy, under the ETC model, to promote placement of PD catheters. Specifically, we are seeking feedback on the following questions:

- What are the key barriers to increased placement of PD catheters?
- How can CMS promote placement of PD catheters in a more timely manner?
- 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?

2. Beneficiary Experience Measure

The ETC Model uses two ESRD facility quality measures; Standardized Mortality Ratio (SMR) (NQF #0369) and Standardized Hospitalization Ratio (NQF #1463). Both measures are currently calculated and displayed on Dialysis Facility Compare, a public reporting tool maintained by CMS. Because data collection and measure reporting are ongoing through claims, there is no additional burden to ETC Participants.

In the Specialty Care Models proposed rule, we considered including the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS)® survey to monitor beneficiary perceptions of changes in quality of care as a result of the ETC Model (84 FR 34565). However, the ICH CAHPS survey includes only beneficiaries who receive in-center dialysis, and specifically excludes the two beneficiary populations that the ETC Model focuses on: Beneficiaries who dialyze at home and beneficiaries who receive transplants.

We are considering the inclusion of a measure to capture the beneficiary experience of home dialysis care. The measure could be either an existing measure or one that CMS would develop. The measure could assess any aspect of the patient experience. The domains could include, but are not limited to, patient satisfaction, patient activation, and quality of life. If a new measure is developed, CMS would like to make it useful to other CMS kidney disease programs.

We seek comments on any aspect of a patient experience measure. Questions to consider include:

- What domains of a patient experience of care with home dialysis would be the most useful to assess and why?
- 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?
- How would a patient experience measure be best used to further the purpose of the ETC Model?
- How should CMS use a patient experience measure to assess the quality of care of beneficiaries?
- How should CMS use a patient experience measure to incentivize improved quality of care in the ETC Model and/or for other CMS programs?

While we will not be responding to specific comments submitted in response to this Request for Information, CMS intends to use this input to inform our future quality measure efforts.

CMS is considering publishing the quality outcomes for the ETC Model. While we seek comments on any aspect of reporting quality data, we specifically want input on the following:

- What is the frequency with which CMS should disseminate the results?
- What should be the unit of analysis for the reported data?

VI. Requests for Information

This section addresses several requests for information (RFIs). Upon reviewing the RFIs, respondents are encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the United States (U.S.) Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted.

Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

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.

Under section 632(b) of ATRA, as amended by section 217(a) of PAMA and section 204 of the ABLE Act, oral-only drugs cannot be incorporated into the ESRD PPS bundled payment until January 1, 2025. In order to provide payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS beginning January 1, 2025, as provided in 42 CFR 413.174(f)(6), we will need to propose refinements to the payment system through notice-and comment rulemaking. A refinement involves revising the patient and facility-level adjustments by changing the adjustment payment amounts based on updated regression analysis using more recent ESRD claims and cost report data. When refinements occur, due to the nature of regression analysis, all patient-level and facility-level adjustments are affected which can impact budget neutrality requirements and impact ESRD facilities differently than if adopted incrementally. Payment system changes can also require extensive efforts by CMS and health care providers to implement. Consequently, we believe CMS and ESRD facilities would best be served if these major payment methodology changes occur as a unified approach for CY 2025.

In order to obtain additional feedback from as wide of an audience as possible, we are soliciting comments from the

public through this proposed rule. We are seeking comments from all perspectives, including differing beneficiary populations of ESRD facilities and ESRD facilities located in remote locations and their infrastructure issues. Obtaining a variety of perspectives enables CMS to ultimately work toward an improved payment methodology for the ESRD PPS that is both patient-data focused and accounts for the changing landscape in providing renal dialysis services to Medicare beneficiaries.

We encourage the public, and all stakeholders to provide comments and recommend approaches that will assist CMS in making refinements to the ESRD PPS through rulemaking in the future. We are soliciting comments this year so that we have time to consider them for potential proposals in the CY 2023 ESRD PPS proposed rule for a CY 2025 implementation.

B. Technical Expert Panels (TEPs)

CMS' contractor held three TEPs to discuss refinements to the ESRD PPS. The TEPs included panelists representing dialysis providers, independent researchers, patient advocates, and representatives from professional associations and industry groups. The first TEP held in 2018 explored the components of the existing ESRD PPS, and identified limitations of the current model. The TEP discussed topics such as current measures of ESRD PPS costs, costs associated with length of dialysis treatment, variations in cost associated with complex patients, facility level drivers of cost, and additional patient attributes necessary for developing a revised ESRD payment model. One of the main goals of the TEP was to identify items and services potentially appropriate for either itemized data collection on claims or improved reporting on the cost reports. The second TEP held in 2019 elaborated on the previous TEP's themes and focused on alternative approaches to measuring the cost of a dialysis session to better reflect treatment-level variation in cost. Topics included measurement of costs for determining case-mix adjustments, wage index, low volume payment adjustments and rural adjustments, TDAPA, outlier determinations, TPNIES, and home dialysis. The third TEP held in 2020 focused on aspects of the ESRD PPS for which refinements or enhancements were being considered. The topics discussed included adult and pediatric case-mix adjustments, low volume payment adjustments, the acute kidney injury payment system, and cost report revisions.

During each TEP, the data contractor presented to the panelists, and the panelists presented to all the TEP participants, innovative methodological approaches that addressed stakeholder concerns about the current payment model and presented alternative approaches with the goal of soliciting specific input for developing a more refined case-mix adjusted payment system. Panelists discussed potential approaches while weighing the ESRD facility burden those approaches may require. Alternative approaches were presented to solicit feedback from panelists about feasibility and acceptability of the options. The TEPs did not provide formal recommendations, but discussion items and suggestions were captured in three subsequent reports. The materials from the TEPs and summary reports can be found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources*.

The following sections of this RFI provide information and solicit feedback specifically on the following topics: Low-volume payment adjustment (LVPA), calculations for case-mix adjustment, the calculation for the outlier payment adjustment, the current pediatric dialysis payment model, recommendations for ESRD PPS and hospital cost report modifications, recommendations for modifying the pediatric cost report, and home dialysis for Medicare beneficiaries with acute kidney injury. While TEP discussions are noted in each section, CMS encourages the public to reference the TEP reports on CMS' website, noted above, for more details.

C. Calculation of the Low-Volume Payment Adjustment (LVPA)

1. Background on the LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS ''shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent.''

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume and to determine the treatment threshold for those facilities identified. After consideration of public comments, we established an 18.9 percent adjustment for facilities that furnish less than 4,000 treatments annually with the intention of encouraging small facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of low-volume under § 413.232(b) as part of the updated regression analysis and found that the facilities still had higher costs compared to other facilities. A regression analysis of CYs 2012 and 2013 low-volume facility claims and cost report data indicated a multiplier of 1.239 percent; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). In CY 2019, 332 facilities received the LVPA and using the most recent available data for CY 2020, the number of facilities receiving the LVPA was 344 as of April 2021.

2. Current LVPA Methodology

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership in the three cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. In order to receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, ''treatments'' mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week of peritoneal dialysis is considered

equivalent to two hemodialysis treatments (80 FR 68994). Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions, with a few exceptions where the deadline is December 31. The November 1 timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. Once a facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the facility (80 FR 69001).

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID–19 PHE. Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we will only consider total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. ESRD facilities will attest that their total dialysis treatments for those 6 months of their cost reporting period ending in 2020 are less than 2,000. The attestation must further include that although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID–19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2.

3. Current Issues and Stakeholder Concerns

ESRD facilities, the Medicare Payment Advisory Commission (MedPAC), and the Government Accountability Office [288] have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.[289] These groups have also have expressed concern that the strict treatment count introduces a ''cliff-effect'' that may incentivize facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.[290]

In addition, we have heard from stakeholders that the eligibility criteria for the LVPA are very explicit and leave little room for flexibility in certain circumstances (85 FR 71442). Finally, some view the attestation process as burdensome to facilities and believe it may discourage participation by small facilities with limited resources that would otherwise qualify for the LVPA.[291] Given these concerns, we have been asked to consider alternative approaches to the LVPA that would reduce burden, remove negative incentives that may cause gaming, and better target facilities that are critical for beneficiary access.

4. Suggestions for Calculating the LVPA

a. Census Tract

During the 2020 ESRD PPS TEP, panelists discussed alternatives to the current LVPA. One methodology discussed utilized census tracts to identify geographic areas with low demand, which suggested increased beneficiary access by incentivizing dialysis organizations to continue operating facilities in otherwise non-viable locations.[292] As discussed during the TEP, an advantage to this approach would be a shift in the focus from identifying low volume facilities to identifying geographical areas, specifically census tracts, with low demand for dialysis.

This census tract methodology often results in a single facility being the only dialysis provider for a number of miles. The process would involve dividing the U.S. into geographic areas based on a reasonable assessment of ESRD beneficiaries' ability or willingness to travel. Latent demand is then calculated by counting the number of ESRD beneficiaries near each facility. ''Near'' is defined by driving time to facilities. Latent demand is calculated by multiplying the number of beneficiaries near an ESRD facility by average number of treatments for ESRD beneficiaries. The LVPA threshold is then applied by determining the threshold of adjusted latent demand. That is, those facilities, which fall below the threshold are LVPA eligible. The panelists noted that this methodology appears administratively simple and could eliminate the burden associated with the LVPA attestation process for facilities and MACs.

b. Low-Volume and Isolated (LVI) Adjustment

In its June 2020 report to Congress, MedPAC recommended that the Secretary replace the LVPA and rural adjustment under the ESRD PPS with a single payment adjustment, a low-volume and isolated (LVI) adjustment, in an effort to better protect isolated, low-volume ESRD facilities that are critical to ensure beneficiary access.[293] A determination that a facility is low volume and isolated would be based on that facility's distance from the nearest facility and its total treatment volume. MedPAC stated that the facilities that would receive the adjustment would be more appropriately targeted. This methodology would be accomplished via a single facility-level regression approach instead of the current two-regression approach utilized by CMS. As an example of how the LVI adjustment would more directly target isolated, low-volume dialysis facilities, the TEP compared the current LVPA and suggested LVI methodologies using 2017 data. In this example, 575 facilities would have been eligible for the LVI verses 1,734 facilities under the current LVPA and rural adjustment methodology.

5. Request for Information on Calculating the LVPA

CMS is considering alternative approaches to the LVPA that directly address stakeholder concerns, and is issuing a request for information to seek feedback on the approaches suggested above, other alternate approaches, and support of the current LVPA methodology. We are soliciting information that will better inform potential future modifications to the methodology. In addition to any other input the public wants to provide regarding the LVPA under the ESRD PPS, we are requesting responses to the following questions.

- Should a distinction other than census tract information be considered?
- What criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility (for example, a threshold of high average cost per-treatment)?
- What are the concerns for facilities that would lose the LVPA under the LVI methodology?
- What are the concerns about the potential for gaming within the LVI methodology?

[288] *http://www.medpac.gov/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf?sfvrsn=0.*

[289] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[290] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[291] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[292] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[293] *http://www.medpac.gov/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf?sfvrsn=0.*

• To the extent that the LVI methodology captures more isolated (and most often rural) facilities, should a separate rural adjustment be maintained?

D. Calculation of the Case-Mix Adjustments

1. Background on the Case-Mix Adjustments

Section 1881(b)(14)(D)(i) of the Act mandates that the single payment system under the ESRD PPS implemented by the Secretary ''shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors.'' The ESRD PPS includes facility-level and patient-level adjustments to the base rate associated with resource utilization and the cost of providing dialysis treatment. The goal of case-mix adjustment is to ensure that payment for a dialysis treatment reflects expected resource use. Payment adjustments protect access to care for the most costly beneficiaries by mitigating financial disincentives to providing that care. The ESRD PPS is a case-mix adjusted, bundled payment model intended to reflect total treatment costs, which consist of formerly separately billable costs and composite rate costs (75 FR 49032). As required by section 1881(b)(14) of the Act, formerly separately billable services were included in the ESRD PPS bundled payment, effective January 1, 2011. Refinements to the current case-mix adjusters were implemented in the CY 2016 ESRD PPS final rule, effective January 1, 2016, and are currently in use.

2. Current Case-Mix Methodology

The current model uses two equations, including a patient-level equation for formerly separately billable costs and a facility-level equation for composite rate costs (75 FR 49083 through 49127). Formerly separately billable services are itemized on the ESRD Facility claim, (Type of Bill: 72x) and include injectable drugs and their oral equivalents plus certain laboratory tests and supplies. Composite rate services, which are captured on the cost report, constitute approximately 90 percent of a treatment's cost and include capital, labor, and administrative costs plus certain drugs, laboratory tests, and supplies (75 FR 49036; 84 FR 38396). Final case-mix adjusters for adults are the weighted average of estimated coefficients from these two equations (that is, patient level and facility level equations). Weights are the fraction of costs that are composite rate versus formerly separately billable. The regression equations and weighted averages are calculated using 2012 through 2013 claims and cost report data. Case-mix factors in the current model include age categories, body surface area (BSA), low body mass index (BMI) indicator, onset status, and comorbidities (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome) (80 FR 68989 through 68992). Facility adjusters include wage index, low volume status, and rural status (80 FR 68972 and 69001).

3. Current Issues and Stakeholder Concerns

Over the last several years, stakeholders have asked CMS to explore a refined case-mix adjustment model for the ESRD PPS, arguing that the existing case-mix adjustors may not correlate well with the current cost of dialysis treatment. They stated that:

• The current adult case-mix adjustors were calculated using old data (that is, 2012–2013 claims and cost report data);

• current adjustors may not align with resource-intensive patient-level services such as isolation rooms, behavioral issues, or neurocognitive issues;

• apportioned composite rate costs (such as labor and capital related costs), from the cost reports, used in the case-mix adjustment are currently only observable at the facility level and do not include patient or treatment level variations; and

• composite rate items are not individually collected on the claim, resulting in the payment not differentiating between the cost of hemodialysis verses peritoneal dialysis, which are affected by different labor and equipment costs.

Other stakeholders raised similar concerns during the TEP meetings. Additionally, panel members questioned the magnitude/significance of age, BMI, and BSA coefficients; the validity of taking weighted average of estimates across the two equations when the joint distribution of composite rate and formerly separately billable costs is not accounted for in the case-mix; and logistical challenges in obtaining the accurate diagnosis and comorbidity data that it is not routinely reported in the 72x claims.

In a comment letter to the Acting CMS Administrator on July 29, 2016,[294] MedPAC noted the current ESRD PPS does not have patient-level variation of composite rate (resource) costs and suggested CMS move to a ''one-equation model'' (that is, a patient-data focused model). MedPAC specifically stated that CMS should develop payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle. CMS is not currently able to implement this recommendation for the ESRD PPS because we do not have data on the charges associated with the components of dialysis treatment costs that vary across patients in the use of the formerly composite rate services.

4. Suggestions for Allocating Composite Rate Costs

CMS has been carefully studying MedPAC's suggestion to base the ESRD PPS on a ''one-equation model'' (that is, a patient-data focused model). CMS has over the years publicly discussed potential changes with our stakeholders who support a patient-data focused model. For instance, during the 2018 and 2019 TEP meetings discussions included using time on machine to address allocation of composite rate costs, case mix, and patient level adjustments. Time on machine would not be used to directly adjust payment; rather, it would be used to apportion composite rate costs (such as labor and capital-related costs) that are currently only observable at the facility level to the patient or treatment level for use in the case-mix adjustment. Data on the time on machine receiving dialysis would allow for a proportionately higher amount of composite rate costs to be allocated to patients with longer dialysis treatment times. During the December 2019 TEP, a panelist indicated that this option would reduce burden since dialysis treatment time (that is, time on machine) is automatically generated by the dialysis machine and easily entered into the patient's medical record. Under this option, a single aggregate number would be reported on each claim. That number corresponds to the total number of minutes the beneficiary spent on dialysis during that claim period. A panelist noted that reporting a single number would minimize provider burden. Panelists reached consensus that the reporting of actual time on

[294] *http://medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cmss-/proposed-rule-on-the-esrd-prospective-payment-/system-and-the-dmepos-competiti.pdf?sfvrsn=0.*

machine offered the best solution for capturing patient-level differences in the cost of dialysis sessions and would be superior to the current case-mix adjusters.

We included discussions about expanding the data elements, moving to a patient-data focused model, and the use of time on machine to determine patient level variation in dialysis treatment costs in the CY 2019 ESRD PPS final rule (83 FR 56963 through 56970) as well as the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400) A comment letter from a large dialysis organization in response to the CY 2019 ESRD PPS proposed rule stated that costs in the remaining category—wages, salaries, and benefits—account for nearly 40 percent of the market basket weight. Additionally, the large dialysis organization noted that these costs represent the majority of expenses associated with dialysis treatment and will vary by patient because they are dependent on dialysis treatment times. The large dialysis organization stated that time on machine was a good proxy for costs in dialysis.

Based on information gathered from our stakeholders and panelists from the first two TEP meetings and comments received based on RFIs in the CY 2020 ESRD PPS proposed rule, CMS took steps towards developing a patient-data focused model. Based on stakeholder input, CMS chose to utilize time on machine to determine patient level variation in dialysis treatment costs. In order to collect this information from ESRD facilities, CMS petitioned the National Uniform Billing Committee (NUBC) for a new value code for time on machine. This value code allows CMS to add time on machine to the ESRD claim. In April 2020, NUBC approved the request. CMS included a requirement to collect time on machine data effective January 1, 2021 in two technical direction letters and two Medicare Learning Network articles. CMS later rescinded the time on machine requirement,[295] but we are discussing this potential requirement in this RFI as a possible future refinement of the ESRD PPS to address allocation of composite rate costs, case mix, and patient level adjustments.

During the 2020 TEP, the data contractor for CMS presented and the panelists discussed potential refinement to concerns regarding the current case-mix adjustment. One of the refinements discussed was collecting time on machine data on the 72x claim using a value code. Specifically, the suggested method includes the costs per beneficiary-facility-month which are the sum of formerly separately billable costs, directly calculated from claims (quantities) and from Part B prices, and composite rate costs for each beneficiary-facility-month, calculated by allocating annual facility costs (less formerly separately billable costs) to the beneficiary-facility-month level using time on machine (duration of all treatments). For some modalities and settings, time on machine is not available and must be imputed. Finally, a regression is run of beneficiary-facility-month costs on case-mix adjusters and facility characteristics. Following a presentation by the data contractor, the panelists agreed that this method would identify a magnitude of factors that best reflect variation in this measure of total cost per treatment. This method would select a set of case-mix adjusters that account for a significant portion of the variance of total costs, subject to intuitive clinical relationship to dialysis treatment costs, reasonable number of risk adjusters, easy to diagnose, identify, or report, and not gameable.

Panelists at the TEPs and stakeholder comments received in response to the CY 2019 ESRD PPS proposed rule believe this one-equation model is more intuitive than current ESRD PPS case-mix adjusters.[296] The suggested case-mix adjusters discussed during the December 2019 and 2020 TEPS are derived relative to variation in total cost of case and that the change in reporting burden is small and would change claims in two ways, including reporting total machine reported treatment minutes and reporting codes for new comorbidities. Finally, stakeholders believe that a magnitude of case-mix adjusters appears to be significantly attenuated relative to the existing ESRD PPS adjusters. As discussed in the TEP Report for the December 2020 TEP,[297] a budget neutral implementation of such a system would result in a 5–10 percent increase in the base rate. Options discussed by the panelists included the one-equation model and keeping the current ESRD PPS case-mix adjustments. CMS is seeking feedback from the public on these options and any additional approaches not yet considered.

5. Request for Information on Calculation of the Case-Mix Adjustments

CMS welcomes the opportunity to inform the public and solicit stakeholder feedback on potential changes to the modeling used to develop the case-mix payment adjustments under the ESRD PPS, in order to inform future model refinements. CMS is considering alternative approaches to calculating the case-mix adjustment that directly address stakeholder concerns, and more appropriately reflects resource use and costs, and is issuing this RFI both to seek feedback on the suggested approach discussed previously, and to solicit information that will better inform future modifications to this methodology. In particular, we are soliciting comments on the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value code to collect time on machine on the claim. In addition to any other input the public wants to provide regarding the calculation of the case-mix adjustment, we are requesting responses to the following questions.

- Which of the five composite rate cost components (that is, age, BSA, BMI, onset of dialysis, comorbidities) are most likely to vary with treatment duration?
- Should new information for these cost components be collected on cost reports, for use in better inferring the composite rate costs associated with treatment duration?
- What are the advantages and disadvantages of obtaining treatment duration information from blood urea nitrogen time on dialysis through the End Stage Renal Disease Quality Reporting System (EQRS) (our new system that has replaced the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb)), versus collecting treatment duration through new fields on claims?
- What challenges would be encountered in reporting treatment duration on claims, using one of the options discussed?
- Are there alternative proxies for resource utilization that can be reported at the patient/treatment level?

E. Calculation of the Outlier Payment Adjustment

1. Background on the Outlier Payment Adjustment

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a

[295] *https://www.cms.gov/files/document/mm11871.pdf.*

[296] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[297] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management. As discussed in section II.B.1.c of this proposed rule, 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 amount and FDL amounts every year under the ESRD PPS. As discussed in the CY 2021 ESRD PPS final rule (85 FR 71439), 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.

2. Current Outlier Payment Adjustment Methodology

The current outlier policy was implemented in the CY 2011 ESRD PPS final rule (75 FR 49134 through 49145) and codified at § 413.237. Under § 413.237, an ESRD facility will receive 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) plus the FDL amount, set each year by CMS.[298] The predicted outlier service MAP amount is the outlier MAP amount published by CMS adjusted for the case mix in the payment year; that is, it is calculated by multiplying the separately billable case mix multipliers by the outlier MAP amount. The outlier MAP and FDL amounts are estimated using the most recent, complete data set available, which are data from 2 years prior to the payment year in question.

The predicted outlier MAPamounts and FDLs create thresholds where, if the outlier MAP amount per treatment on the claim is above the threshold, there will be a per-treatment outlier payment equal to 80 percent of the amount exceeding the threshold. The loss-sharing percentage was set at 80 percent in the CY 2011 ESRD PPS final rule (75 FR 49144) to make it consistent with the loss-sharing percentages in other Medicare payment systems.

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).

The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundled payment: (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 that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended. Beginning January 1, 2021, calcimimetics became outlier services (85 FR 71405).

In the CY 2011 ESRD PPS final rule (75 FR 49064 through 49065), CMS explained that it estimates an ESRD facility's costs based on most recent available data. Since the rulemaking is done in the year prior to the effective date, the most complete available data would be from the year before. This means that for CY 2022 (as discussed in section II.B.1.c of this proposed rule), CMS is proposing to recalibrate the outlier MAP and FDL amounts for each calendar year using data from 2 years prior, which is the most recent and complete claims data. This methodology assumes consistent utilization over time, that is, it assumes that 2020 utilization rates for ESRD PPS outlier items and services are the same as those for 2018. However, the use of ESRD PPS outlier items and services has in fact declined each year since the implementation of the ESRD PPS.

For example, the CY 2020 FDL amount ($48.33 for adult patients) was calculated and added to the predicted MAP to determine the outlier thresholds using 2018 data. However, ESRD PPS outlier spending continued to fall from 2018 to 2020. Consequently, outlier payments for CY 2020 claims comprised only 0.6 percent of total ESRD PPS payments, demonstrating that the use of 2018 data results in thresholds too high to achieve the targeted 1.0 percent outlier payment. Outlier payments for the adult population have constituted less than 1.0 percent of total ESRD PPS payments since such payments began in 2011.[299]

3. Current Issue and Stakeholder Concerns

As the outlier payments have consistently landed below the targeted 1.0 percent of total ESRD PPS payment threshold, stakeholders have noted that the methodology currently used to calculate the outlier results in underpayment to the providers, as money was removed from the base rate to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). Therefore, they have urged us to adopt an alternative modeling approach, one that accounts for declining trends in outlier-eligible items and services spending over time. MedPAC echoed these concerns in a comment letter in response to the CY 2021 ESRD PPS proposed rule, where it also suggested that the introduction of calcimimetics as outlier-eligible items could perpetuate the pattern of underpayment. MedPAC stated that if calcimimetic use decreases between 2019 (when the products were paid under the ESRD PPS using the TDAPA) and 2021 (when the products will be paid as part of the ESRD PPS base rate), the outlier threshold will be set too high, and outlier payments will be lower than the 1 percent of total 2021 payments.

4. Suggestions for Outlier Payment Adjustment

During the second and third annual TEP meetings convened by the CMS contractor in 2019 and 2020, panelists discussed concerns regarding the current outlier adjustment policy and alternative methodologies to achieve the 1 percent outlier target. Some TEP panelists and stakeholders have strongly advocated that we establish a new outlier threshold using alternative modeling approaches that account for trends in separately billable spending over time. Overall, panelists expressed support for any change to outlier calculations that result in total outlier payments closer to the target.

[298] The FDL amount is the amount by which an ESRD facility's per-treatment Medicare allowable payment amount for furnishing ESRD outlier services to an adult/pediatric beneficiary must exceed the adult/pediatric predicted ESRD outlier services Medicare allowable payment amount to be eligible for an outlier payment.

[299] Outlier percentages for the pediatric population have high variability from year to year, but have consistently met or exceeded the 1.0 percent target. The methodological modifications in this RFI do not apply to the pediatric population.

Panelists noted that the underlying basis of an alternative methodology could be to re-examine the assumption of constant utilization over time. Unlike the current outlier methodology that predicts FDL amounts using a single year of claims data, this approach allows for the modeling of the MAP amounts as they change over a longer period of time. CMS has received a number of suggested techniques that could be employed to reach the 1.0 percent target more predictably.

One of these suggestions is a calculation of ''after the fact'' FDLs that would achieve the 1.0 percent outlier target for each year included in the FDL calculation. This has been referred to as the retrospective FDL, which would be lower than the FDLs published in the final rule for each corresponding year. This calculation would be used for future outlier calculations. For more information, please refer to the TEP reports here: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources*.

Data presented during the TEP meeting showed that using the three most recent years to simulate FDLs and outlier payments for 2020 resulted in an FDL amount for adults of $33.83 and a MAP amount of $37.41, respectively. By contrast, the 2020 FDLs and MAPs published in the CY 2020 ESRD PPS final rule (84 FR 60649) were $48.33 and $35.78, respectively. The simulated outlier percentage for 2020 using the alternative methodology was 0.8 percent. The actual outlier payment percentage made for 2020 claims was 0.6 percent. Therefore, the alternative methodology results in an outlier percentage that is closer to the 1.0 percent target in the adult population.

6. Request for Information

CMS is considering potential revisions to the calculation of the outlier threshold to address stakeholder concerns, and is issuing a request for information both to seek feedback on the approach suggested above, and to solicit information that will better inform future modifications to the methodology. In addition to any other input the public wants to provide for calculating the outlier payment adjustment, we are requesting responses to the following questions.

• An alternative approach could be to estimate the retrospective FDL trend by using historical utilization data. The example above was constructed by using 2016–2018 data. There is flexibility in the time used to estimate this trend. The data must contain at least 2 years' worth of claims data and may begin as early 2011. Additionally, it must end with the most recent year with complete data (typically 2 years before the year in which the FDL will take effect).[300]

++ How many years of data should be included in calculation of this trend to best capture changes in treatment patterns?

• The simulation of the FDL can be improved by better anticipating changes in utilization of ESRD outlier services. What are the factors that affect the use of ESRD outlier services over time, and to what extent should CMS try to forecast the effect of these factors?

• ESRD beneficiaries can now choose to enroll in Medicare Advantage.

++ Please describe any anticipated effects of this enrollment change on the use of ESRD outlier services in the ESRD PPS.

• Adoption of the suggested methodology may account for systematic changes in the use of high-cost outlier items. However, inherently unpredictable changes may still push the outlier payment off the 1.0 percent target.

++ Please comment on the acceptability of the below payment adjustment methods.

++ Payment reconciliation—in the form of an add-on payment adjustment or a payment reduction—might be necessary to bring payments in line with the 1 percent target.

++ An add-on payment adjustment would be distributed after sufficient data reveal the magnitude of the deviation (1 year after the end of the payment year). The distribution of these monies could be done via a lump sum or via a per-treatment payment add-on effective for 1 year. This add-on payment adjustment would be paid irrespective of the outlier claim status in that year.

++ A payment reduction could take the form of a reduction in the base rate, also to be applied 1 year after the end of the payment year.

F. Calculation of the Pediatric Dialysis Payment Adjustment

1. Background on the Pediatric Dialysis Payment Adjustment

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment for pediatric providers of services and renal dialysis facilities. Below we discuss the current ESRD PPS with regard to ESRD facilities that furnish renal dialysis services to pediatric patients, and request information on specific approaches as well as other topics related to developing a pediatric payment adjustment under the ESRD PPS.

Prior to implementation of the ESRD PPS, payment for dialysis treatments was made through a composite rate per treatment that was based on cost report data and did not account for differences among patients with ESRD (48 FR 21254). The initial payment rates were established at $127 per treatment for independent facilities and $131 for hospital-based facilities, which reflect the costs incurred by dialysis facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether furnished by hospital-based and independent facilities in a facility or at home.

In addition, we provided a process under which facilities with costs per treatment in excess of their composite rates could seek exceptions to those rates under specified circumstances in §§ 413.182 and 413.184. For example, when a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies necessary to meet special medical needs of the facility's patients could qualify for an exception rate. Under § 413.182, CMS could approve exceptions if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to its patient mix. As a result of these provisions, many pediatric facilities secured an exception rate and were paid the exception rate until the transition to the ESRD PPS ended in CY 2014.

Section 1881(b)(12) of the Act, added by section 623(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Secretary to implement a basic case-mix adjustment to an ESRD facility's composite payment rate reflecting a limited number of patient characteristics. On August 5, 2004 and November 15, 2004, we published a proposed rule and final rule with comment period (69 FR 47487 through 47730 and 69 FR 66235 through 66915), respectively, implementing the provisions affecting the composite payment system. The development and

[300] The example uses CY 2020 to judge the performance of the alternative methodology. The most recent year with complete data when the 2020 FDL was determined was 2018.

application of the basic case-mix adjustments, using regression-based adjustment factors for the patient variables of age, BSA and BMI are explained in each of those rules (69 FR 47529 through 47531 and 69 FR 66323 through 66324, respectively). The product of the specific adjusters for each patient, multiplied by the otherwise applicable composite payment rate, yielded the basic case-mix adjustment as required by statute. The basic case-mix adjusted composite payment system was effective April 1, 2005 and continued until the ESRD PPS was implemented on January 1, 2011.

As we explained in the CY 2005 ESRD PPS final rule with comment period (69 FR 66326 through 66327), we attempted to develop case-mix adjusters for outpatient patients with ESRD under age 18. However, we found that for the approximately 600 Medicare pediatric patients for whom claims were available from 2000 through 2002, the results were highly variable and statistically unstable, and therefore, inappropriate for the development of case-mix adjusters in accordance with the same methodology otherwise applicable to adult Medicare patients with ESRD.

For this reason, we described an alternative methodology we used to develop a 62 percent pediatric increase (that is, an adjustment factor of 1.62) applied to the composite payment rate per treatment for any facility furnishing outpatient dialysis services to pediatric patients. That factor was based on the average amount of the atypical services exceptions granted for 20 ESRD facilities, each of which sought and received an exception for the atypical costs incurred for the treatment of outpatient pediatric patients, compared to the average unadjusted composite payment rate (that is, the payment without regard to exception amounts) for these same 20 facilities. We explained that application of the pediatric adjustment factor of 1.62 in lieu of an explicit pediatric case-mix adjustment was temporary, and would be eliminated once an appropriate methodology, preferably one applicable to both pediatric and adult Medicare patients, could be developed.

In the CY 2011 ESRD PPS proposed rule (74 FR 49986 through 49987), we proposed a pediatric payment methodology with comorbidity adjusters. However, in the CY 2011 ESRD PPS final rule (75 FR 49130 through 49134), in response to public comments, we explained that instead of using the regression-based composite rate multiplier of 1.199, we established the pediatric payment adjusters using the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate services in CY 2007 based on the 872 pediatric dialysis patients reflected in the data. That is, the average CY 2007 MAP for composite rate services for pediatric dialysis patients was $216.46, compared to $156.12 for adult patients. We used CY 2007 data consistent with our determination that 2007 represented the year with the lowest per patient utilization of dialysis services in accordance with section 1881(b)(14)(A)(ii) of the Act. We developed payment adjusters using the variables of age (that is, <13 and 13–17) and modality (peritoneal dialysis or hemodialysis).

In the CY 2016 ESRD PPS final rule (80 FR 68968), we refined the ESRD PPS in accordance with section 632(c) of ATRA, which required CMS to conduct an analysis and make appropriate revisions to the case mix payment adjustments. We analyzed the case-mix payment adjustments under the ESRD PPS and revised the payment adjusters using CYs 2012 and 2013 ESRD claims and cost report data. For pediatric dialysis, we used the same methodology that was used for the CY 2011 ESRD PPS final rule, except for the use of more recent data years (2012 through 2013) and in the method of obtaining payment data. Specifically, we used the projected MAP based on 2013 claims to calculate the ratio of pediatric total MAP per session to adult total MAP per session. The resulting adjustment factors reflected an 8.21 percent increase to account for the overall difference in average payments per treatment for pediatric patients. The pediatric adjusters that were finalized for CY 2016 and are currently in effect are:

<13 peritoneal dialysis = 1.063
<13 hemodialysis = 1.306
13–17 peritoneal dialysis = 1.102
13–17 hemodialysis = 1.327

2. Current Issues and Stakeholder Concerns

Since 2015, we have continued to hear from organizations associated with pediatric dialysis about the undervaluation of pediatric ESRD care, which requires significantly different staffing and supply needs from those required to deliver ESRD care to adults. These organizations support CMS efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. Commenters have also suggested that we reinstate the exceptions process that would provide individual hospitals and ESRD facilities with their own payment rate based on their costs. We note that this approach would require a statutory change because section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to all ESRD facilities.

Stakeholders have informed us that costs unique to pediatric dialysis are not adequately captured in current cost reports or claims, and therefore are not accounted for in the pediatric adjustments. In addition, they have explained that pediatric dialysis often requires developmental and behavioral specialists, pediatric dieticians, and social workers, and that pediatric comorbidities require unique specialized care. Further, pediatric nephrologists have told CMS that pediatric patients disproportionately receive treatment in hospital-based facilities, but the hospital cost report (CMS Form 2552–10) does not distinguish pediatric and adult dialysis cost.

One organization suggested that we expand the pediatric age groups and create either pediatric modifiers or a pediatric add-on payment by age group. Alternatively, the organization suggested that we create a pediatric-specific ESRD bundle that would allow for full accounting of costs for pediatric staffing and specialized equipment, and the economic implications of pediatric medical comorbidities that are not addressed in the current PPS. In order to engage dialysis stakeholders in advance of rulemaking, CMS' data contractor conducted TEP discussions for the past three years on various dialysis payment approaches and issues. For the 2020 TEP, one of the discussion topics was pediatric dialysis. Based on discussions and meetings with stakeholders and TEP panelists, the contractor performed several analyses on pediatric dialysis to inform the TEP discussion. The analyses confirmed many of the challenges reflected in stakeholder comments regarding pediatric dialysis.

For example, a small number of facilities provide 95 percent of pediatric dialysis treatments (approximately 100) and those pediatric facilities are hospitals, mostly children's hospitals. Pediatric treatments are split between home peritoneal dialysis (mostly for children younger than 13) and in-center hemodialysis (for older children 13–17). One analysis, using cost report data, found that the median registered nurse/licensed practical nurse hours per-treatment is higher in pediatric facilities and pediatric comorbidities require more (specialized) staffing. Dialysis for

pediatric patients is furnished in hospitals, primarily children's hospitals or in large dialysis organization facilities. For more information, please refer to the TEP reports.

The contractor performed analyses using the expanded age groupings suggested by the commenters and found that finer stratification of the age groups reveals differences in cost per treatment. The contractor found that the median cost per treatment for the pediatric population using the same methodology used in the 2016 refinement but using more recent data (2018 and 2019) resulted in significant differences in cost among the pediatric age categories. The contractor also found that the median cost per treatment for the pediatric population using the national average treatment duration, the relationship between total cost per-treatment and age is consistent with stakeholder comments.

3. Suggestions for the Pediatric Dialysis Payment Adjustment

During the December 2020 TEP, three approaches were discussed among the panelists that could potentially lead to a more accurate estimate of pediatric dialysis costs under a revised payment model: (1) The addition of pediatric-specific case-mix adjustment multipliers; (2) the creation of a separate payment bundle for pediatric ESRD treatment costs; and (3) revisions to current data collection practices.

To illustrate how the refined model would incorporate the pediatric population, the contractor applied the model using each of the two current age groupings, resulting in an increased effect of age on costs, with multipliers of 1.61 and 1.74 for age <13 years and age 13 to 17 years, respectively, compared to the reference adult population. Please refer to the TEP report [301] for more specific information on the analyses and discussion.

Stakeholders suggest that the variables affecting pediatric dialysis costs are sufficiently different from those associated with adult dialysis costs, and that a separate payment system may be warranted. Although the creation of a pediatric bundle or separate pediatric ESRD PPS may improve cost estimates for the pediatric population, if there were a statutory change to authorize this separate payment system, the time required for implementation would be substantial due to the subsequent need for new, pre-implementation data collection, which providers may find burdensome.

The TEP panelists also discussed several modifications to the cost reports that they believe would better capture resources utilized in the pediatric dialysis setting. These include adding lines itemizing pediatric specific labor categories and pediatric specific supplies, clarifying cost report instructions as they pertain to pediatric dialysis, and better aligning the freestanding facility cost report with the hospital cost report. Although these changes have the advantage of being highly feasible to implement, stakeholders have noted that uptake may take additional time, as pediatric facility accounting and billing staff are not generally familiar with Medicare cost reports. Furthermore, stakeholders have noted that changes to the freestanding facility cost report would be of limited value, since pediatric dialysis primarily takes place in hospital-based facilities.

Panelists generally favored the addition of pediatric case-mix adjustment multipliers. One panelist noted that prior to the current case-mix adjustment; the multiplier applied to pediatric facilities was based on actual costs incurred during treatment that were more accurate than the costs being reported currently. The case-mix adjustment multipliers presented during the TEP were similar to the multipliers from the prior payment method, which the panelist found encouraging.

However, there was shared concern among TEP panelists that there will continue to be underpayment for pediatric dialysis patients. One panelist noted that time on dialysis may not accurately reflect all costs, and may be especially misleading for those under 2 years of age. For this patient population, expenditures on some fixed costs (for example, dialysate) will decrease, but staffing costs would be considerably higher, as they require one-on-one nursing and child life specialists and are more difficult to initiate on dialysis. Therefore, panelists expressed the concern that the multipliers based on duration of treatment would not accurately reflect costs. Another panelist noted that certain state laws with personnel requirements for pediatric dialysis could also increase costs.

Panelists supported moving forward with the cost report and case-mix multiplier modifications due to the burden of implementing a new bundle. One panelist noted that a time and motion study attempted by their dialysis organization failed, as there was a high degree of variation among facilities. However, another panelist described their facility's success in securing additional funding for their pediatric dialysis unit as a result of a time and motion study.

Panelists affirmed that accounting and billing departments at children's hospitals are not well equipped to accurately complete Medicare cost reports and suggest that this may be due both to their general lack of familiarity with Medicare (one panelist noted that only 30 percent of pediatric patients are Medicare beneficiaries) and the cost report's current structure.

One panelist cautioned that because most pediatric dialysis is delivered in the hospital setting, if the revised hospital cost report does not include the modifications recommended for the dialysis facility's cost report, pediatric expertise for dieticians, social workers, child life specialists, and behavioral specialists may remain overlooked. Despite this, panelists expressed the desire to move forward with the suggested cost report modifications to improve pediatric payment, which is presented later on in the preamble in section VI.H of this proposed rule.

4. Request for Information for Pediatric Dialysis Payment

CMS is soliciting feedback from the public on pediatric dialysis payment. In addition to any other input the public wants to provide for the pediatric dialysis payment adjustment, we are requesting responses to the following questions.

- Does the magnitude of total costs and pediatric multipliers reflect ESRD facilities' actual incurred costs? If not, what specific costs are not being reported on claims and/or cost reports?
- Is there sufficient variation in composite rate costs among pediatric patients to justify use of a proxy to distribute facility-level composite rate costs to individual treatments?
- If duration of treatment is not a valid proxy for composite rate costs per treatment, what are alternative proxies to consider?
- What, if any, are the specific concerns about incorporating pediatric patients into the estimation of multipliers for both the adult and pediatric populations?
- What are the issues facing pediatric billing and accounting staff with regard to completion of claims and cost reports? How can these problems be remedied?
- Are there additional costs factors for pediatric patients that are not adequately captured on the 72X claim?

[301] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

G. Modifying the ESRD PPS and Hospital Cost Reports

1. Special Audit Adjustment Summary

a. Background

Throughout the years, we have received comments about updating the Medicare Renal Cost Reports (CMS-Form-265–11). Data from the Medicare Renal Cost Reports is received by the Hospital Cost Report Information System (HCRIS). Stakeholders have asserted that the cost reports need more granularity to align resource use with payment. In addition, section 217(e) of PAMA mandated an audit of Medicare cost reports beginning during 2012 for a representative sample of providers of services and renal dialysis facilities furnishing renal dialysis services. The following discusses CMS's audit process and findings.

Organizations that consist of multiple ESRD facilities or business entities may have Home Offices that furnish central management and administrative services (for example, centralized accounting, purchasing, personnel services, and management) to other organizations within the chain. To the extent that the Home Office furnishes services related to patient care to a provider, the reasonable costs of such services are included in the ESRD facility's cost report and are reimbursable as part of the ESRD facility's costs. The CMS' Office of the Actuary (OACT) selected a sample of 1,479 freestanding ESRD facilities from five Home Offices of large dialysis organizations for the cost audit. A contractor performed cost audits of these ESRD facilities in September of 2015. All audits were completed by September of 2018.

Upon completion of the audits, adjustments for unallowable costs were made by CMS's Office of Financial Management to the ESRD cost reports and reflected in the HCRIS data. As of March 2020, 1,395 of the 1,479 ESRD facilities had complete HCRIS data (that is, containing both pre-and post-audit information). A summary of the audit adjustments include Home Office costs, drugs, and treatments, which are discussed in this section.

b. Home Office Cost

Of the ESRD facilities sampled, 1,278 of 1,479 received an allocation of Home Office costs from the five Home Offices selected for review. Any adjustments of unallowable Home Office costs would flow down and be reflected in the ESRD facilities' cost reports.

c. Adjustments

Using the HCRIS data, of the 1,395 ESRD freestanding facilities analyzed, a total of $147.5 million of unallowable costs were removed from the total costs reported on Worksheet A. Noteworthy adjustment areas included $136.5 million of the unallowable costs initially reported in the administrative and general cost center on Worksheet A, with $75 million of this $136.5 million pertaining to related-party adjustments recorded on Worksheet A–3. Of the $75 million, $72 million were for Home Office costs, including disallowed related party costs associated with Home Office and management fee adjustments. Some of the major adjustments noted at the Home Office level reviews included the following: Unsupported documentation; related-party management fees; lobbying expense; taxes for items not related to patient care; executive compensation in excess of reasonable guidelines, and related party laboratory costs, which were reduced to cost. Other certain non-allowable items included: Advertising, legal fees interest expense and financing fees, corporate travel/lodging/relocation, various consulting fees, business development expenses; insurance settlement payments; insurance expenses (malpractice, etc.).

d. Drugs

In general, there were minimal adjustments to drugs cost and these were made to both drug expense and drug rebates (<1.0 percent in aggregate). The top five ESRD dialysis organizations were examined based on total reimbursable cost and average cost per treatment for adult hemodialysis (the most common treatment type). No material adjustment was made to total number of treatments. However, there was a significant decrease in the average cost per treatment because of material adjustments made to the total allowable costs. The number of Epoetin Units furnished during the Cost Reporting Period (reported on Worksheet S–1, Line 14) was reduced by approximately 13 percent in aggregate. However, the majority of these adjustments related to two specific facilities, with one of the facilities having the total amount reported reduced to zero. The number of Aranesp Units furnished during the cost reporting period (reported on Worksheet S–1, Line 15) was reduced by approximately 18 percent in aggregate. However, the majority of these adjustments related to two specific facilities, both of which were reduced to zero.

e. Treatments

The total number of treatments not billed to Medicare and furnished directly (Worksheet S–1, Line 1) decreased by an average of 2.6 percent. However, the total number of treatments not billed to Medicare and Furnished under Arrangement (Worksheet S–1, Line 2) had no change. The average cost per treatment among the various types of treatments and categories appears to have decreased by an average of 1.75 percent. However, some of the adult average costs per treatment related to home program continuous ambulatory peritoneal dialysis increased after the audit by an average of 1.5 percent.

Based on this audit, our cost report data was corrected.

2. Suggestions for Modifying the ESRD PPS and Hospital Cost Reports

a. Independent Dialysis Facility Cost Report

During the 2020 ESRD PPS TEP, the data contractor engaged the panelists in a discussion regarding potential revisions to the Independent Dialysis Facility Cost Report (CMS Form 265–11). (See *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Renal-Facility-265-2011-form*.) These potential revisions, which would support the efforts to develop a refined case-mix model for the ESRD PPS, are described in this section. CMS seeks input from the public on the feasibility of implementing these suggestions in freestanding ESRD facilities. These potential reporting changes would require facilities to allocate composite rate costs across settings and modalities. Taken together, the resulting cost report data would enable the determination of variation in costs across patient types (by risk groups and dialysis modalities).

In the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400) CMS sought input on identifying components of composite rate costs, including specific facility-level costs that, in combination with treatment-level data, could be used to understand variation in dialysis treatment costs across patients. While composite rate costs constitute nearly 90 percent of total treatment costs, they are not itemized on claims, leaving facility cost reports as the only source of information on these costs. Commenters' suggestions included adding detail and stratifying the reporting detail of selected composite rate costs by setting and modality and providing additional data to determine variation in treatment costs across patient risk groups and treatment modalities.

The facility-level cost components of interest include capital costs related to dialysis machines and other equipment used in dialysis treatment, labor costs, and supply costs. Based on the input received and further analysis conducted by the data contractor, several specific changes to the cost reports were suggested. These include changes in the reporting of composite rate components: (1) Capital costs for dialysis machines and related equipment, (2) direct patient labor costs, (3) administrative and managerial costs, and (4) differentiation of separately billable from composite rate laboratory and supply costs. The suggested changes would also require reporting of these costs by modality. While the ''step down'' worksheet (Worksheet B–1) in the current cost report separates capital and labor costs by modality, this separation is based on proportionally allocating costs according to a specified statistical basis (for example, treatment counts), rather than the reporting of actual capital and labor resources associated with each modality. The data contractor and panelists agreed that changing the specifications in the instructions to the cost report to indicate that the allocations be made on the basis of actual resource use, would allow for a better estimation of component costs per treatment and analysis of how these costs vary among patient groups and across modalities.

b. Costs for Capital-Related Assets That Are Dialysis Machines

Based on stakeholder feedback, CMS would like to understand difficulties ESRD facilities have in reporting capital costs, particularly as they relate to dialysis machines. Both TEP panelists and dialysis associations have suggested that modifications to reporting of the capital costs of dialysis machines focus on two goals. The first goal is to improve the fidelity and comparability of dialysis machine capital cost reporting across individual facilities. They suggested that this would be achieved with more specific instructions for completing the cost report. The second goal is to ensure CMS's ability to distinguish between dialysis machine capital costs among various modalities and dialysis settings in a way that preserves fidelity and comparability among facilities. This could be achieved with revisions to the cost report itself. As suggested by panelists and some stakeholders, to achieve these ends, revisions to the cost report related to dialysis machine capital costs might include:

- Improve the instructions related to the reporting of dialysis machine capital costs.

++ For purchased equipment: Specify purchase price, depreciation, maintenance, repair, insurance, replacement.

++ For rented equipment: Specify rental rates, maintenance, repair, insurance, rent escalators.

- List and stratify the costs of capital equipment used in dialysis treatment by setting and modality.

++ Differentiate between rented and purchased equipment.

++ Differentiate among machines used in-facility and in the home setting.

++ Differentiate machine costs in the home setting by modality for home hemodialysis and home peritoneal dialysis.

++ Include water treatment machines and indicate location of use: Home versus in-facility.

- Location in Form 265–11

++ Expand Worksheet A, Line 6.

++ Revise instructions for Worksheet A–1, adding specificity corresponding to item definitions discussed earlier in the preamble.

c. Direct Patient Labor Allocation

Currently, the cost report does not stratify full-time equivalent (FTE) hours for direct patient care staff by dialysis modality. It also does not include several job classifications that are commonly found in present-day ESRD facilities.

At present, the statistical basis for allocating direct patient care costs is hours of service (as seen in Worksheet B–1, Column 5). Using this metric and allocating resource (or labor) use proportionally by labor hour (independent of labor type) can result in miscalculation of labor costs by modality. For example, if labor for the provision of home dialysis is on average more expensive than labor for in-facility hemodialysis, then a strict by-hour cost allocation will result in a calculation of home dialysis labor costs that is less costly per-hour than in practice. Suggestions have included that by substituting FTE for hours for each appropriate direct patient care labor category, and using labor categories that more accurately reflect current staffing patterns in ESRD facilities, any potential misrepresentations of relative labor costs across modalities can be remedied.

To this end, CMS has received a suggestion to consider the use of Bureau of Labor Statistics (BLS) occupational categories for outpatient care centers to remedy this situation, as it would provide up-to-date job classifications that the comment believes would better correspond to staffing patterns in ESRD facilities than the currently used Inpatient Prospective Payment System job categories. Selecting BLS occupational categories for outpatient care centers could be added or substituted in Lines 23–31 on Worksheet S–1 of CMS Form 265–11 to reflect current staffing patterns, and columns could be added to separately report home dialysis FTE and in-facility dialysis FTE for each relevant occupational category. Additional labor categories might include registered nurses with varying credentials, dieticians, pharmacists, and nurse practitioners and other intermediate-level providers, as appropriate.

d. Managerial and Administrative Labor Allocation

The data contractor and TEP panelists discussed Medicare cost report's non-direct patient care positions, specifically the current managerial and labor allocation. They made recommendations for differentiating high-cost management from lower-cost administrative and clerical functions, which included a set of potential revisions to bring management and administrative labor categories up to date using occupational categories that reflect current usage in dialysis facilities.

As with the direct patient labor allocation above, suggestions include the use of BLS occupational categories for outpatient care centers that correspond to the roles employed in contemporary dialysis facilities. Suggested additions to these job categories might include business and financial operations personnel, office and administrative workers, facility support workers, and programmers and analysts. With more accurate data, it may be possible to determine how management and administrative costs are differentially allocated across facilities (by region and treatment-type specialization). These suggested changes to managerial and administrative job categories would be made to Worksheet S–1, Lines 31–34.

e. Supplies and Laboratory Services

While composite rate and separately billable drug costs are differentiated on the cost report, supplies and laboratory tests are not differentiated. Supplies comprise approximately 10 percent of composite rate costs. To bring uniformity to the reporting of drugs, laboratory tests, and supplies, we have received suggestions that supplies and laboratory tests be similarly stratified. These costs are currently reported on Worksheet B/B–1. Specifically,

stakeholders have suggested the following changes: (1) Add separate columns differentiating composite rate from separately billable supplies (Worksheet B/B–1, Column 7–8); (2) add separate columns differentiating composite rate from separately billable laboratory services (Worksheet B/B–1, Column 9–10).

3. Request for Information on Independent Facility Cost Report

CMS invites comments on the suggested changes to the Independent Facility Cost Report (CMS Form 265–11), as described earlier in this section of the proposed rule. In addition to any other input the public wants to provide on modifying the Independent Facility Cost Report, we are requesting responses to the following questions.

• What challenges, including operational difficulties, do ESRD facilities currently face in reporting capital costs:

++ In general.

++ Due to inadequate instructions:

—Which instructions should be revised for clarity?

—Of those above, which are most problematic?

++ In responding, please indicate whether you are representing the views of a

—Large dialysis organization.

—Regional organization.

—Independent and/or rural facility or another entity.

++ What level of expertise do personnel typically filling out cost reports have:

—With cost accounting principles and practices?

—With health care cost accounting principles and practices?

—With operational details of how capital equipment is used in their ESRD facility?

++ Are accounting record-keeping systems currently used by ESRD facilities adequate to the task of responding to current and contemplated (in this RFI) cost reporting requirements?

• What challenges, including operational difficulties, would ESRD facilities face:

++ In reporting dialysis-related machine costs by modality and location?

++ In determining the facility level distribution of direct patient labor FTE across modalities for each type of direct patient labor?

++ In reporting separate costs for composite rate supplies and separately billable supplies?

++ In reporting separate costs for composite rate laboratory services and separately billable laboratory services?

• What categories of direct patient care labor, such as registered nurses (North American Classification System (NAICS) 29–1141) and dieticians (NAICS 29–1031), are routinely employed by your dialysis facility and which can be documented in cost reports? Please provide the specific Bureau of Labor Statistics NAICS code associated with each labor category for outpatient care centers found at this website: *https://www.bls.gov/oes/current/naics4_621400.htm*.

• Please detail the specific categories of administrative and management personnel currently employed by your ESRD facility and which can be reported on CMS Form 265–11. Please provide the specific Bureau of Labor Statistics NAICS code associated with each labor category for management (*https://www.bls.gov/oes/current/naics4_541600.htm#11-0000*) and administrative (*https://www.bls.gov/oes/2018/may/naics3_561000.htm*). Please indicate if relevant labor categories are not represented here and how these categories can be documented and reported on CMS Form 265–11.

• Stakeholders have commented on other categorical costs that are not reported on the cost report. These include missed treatments and use of isolation rooms.

++ Specifically, please comment on adding reporting of (1) missed treatments, and (2) maintenance of isolation rooms.

++ Where on CMS Form 265–11 should these items be inserted (if at all)?

• What challenges would hospital-based facilities face were the hospital-based cost report to be revised to harmonize with the changes suggested for the independent facility cost report? How can the two cost reporting forms be brought into congruence as related to: Dialysis related equipment, direct patient care, administrative labor, drugs, laboratory services, and supplies?

• Costing accuracy is difficult to achieve for home dialysis. The suggested revisions described above strive to differentiate costs among the different modalities. Are there other means for facilities to report more accurate cost data for home dialysis modalities? Specifically, how can staff time dedicated to home dialysis treatment be better reported?

• What other changes might be made to the cost report to better differentiate costs across modalities and patient risk groups?

H. Modifying the Pediatric Cost Report

1. Background

Pediatric composite rate costs are not differentiated from adult costs on hospital cost reports, while some pediatric-specific costs are itemized on the existing free-standing cost report. Using CY 2019 cost report data, CMS' data contractor computed total and component specific cost per treatment for hemodialysis-equivalent treatments, stratified by modality, and obtained the ratio of pediatric to adult cost per treatment for each dialysis facility that reported both adult and pediatric treatments. The results indicate that there is variation in costs across composite rate cost components for pediatric and adult treatments. Overall the cost ratio of pediatric to adult treatment costs is 1.58,[302] indicating that pediatric treatments are more expensive to administer than adult treatments. For one cost component in particular, supplies, the ratio is 7.30,[303] indicating much higher costs for pediatric dialysis supplies than for adult supplies. Further analysis, however, revealed that a substantial portion of facilities does not differentiate between adult and pediatric costs in their cost report accounting. Overall, we found that 13 percent of facilities that treat both pediatric and adult dialysis patients do not differentiate costs between the two age groups.

2. Suggestions for the Pediatric Cost Report

In response, CMS is considering that two types of changes be made to the hospital and free-standing ESRD facility cost report that would facilitate the separate reporting of adult and pediatric treatment costs: (1) Changes that differentiate pediatric from adult composite rate component costs, and (2) changes that allow for further differentiation of component costs by modality and age group within the pediatric population. The potential revisions for which stakeholder input is being sought include the addition of select direct patient care labor categories, which correspond to the type of labor typically employed by pediatric dialysis facilities, and the differentiation of pediatric supplies and equipment.

Specifically, CMS is considering adding the following staff categories to CMS Form 265–11, Worksheet S–1, Lines 21–31 (Renal Dialysis Facility—Number of Employees (Full Time Equivalents)): Pediatric dialysis nurses and nurse practitioners, pediatric social workers, pediatric dieticians, child life specialists, teachers, and pediatric

[302] The fraction would be 158/100, that is $1.58 is spent overall on pediatric dialysis treatments for every $1.00 spent for adult patients.

[303] $7.30 is spent, overall, on supplies for a pediatric dialysis treatment for every $1.00 spent on supplies for an adult treatment.

dialysis unit coordinator. We have also received recommendations that additional columns be added to this section of the cost report to differentiate pediatric home dialysis and in-facility dialysis.

With regard to pediatric supplies and equipment, stakeholders have suggested that there be clear differentiation of supplies used in dialysis treatment of pediatric patients, which vary in type and size, from those used with adult dialysis patients. Stakeholders have further indicated that there is added cost involved with the stocking of the range of sizes and types of supplies needed for this population. Categories of supplies for which there is a significantly increased cost for the pediatric population include: Dialyzers, catheter kits, fistula needles, saline flushes, monitors for vitals, blood pressure cuffs and items used to occupy children during their treatment.

Pediatric nephrologists have noted that these suggested revisions would have the greatest impact on the hospital cost report, which currently does not differentiate pediatric from adult dialysis patients. Approximately two-thirds of pediatric dialysis treatments take place in the hospital or medical center setting.

3. Request for Information on the Pediatric Cost Report

CMS invites comments on the potential changes to cost reports, described previously in this section of the proposed rule, as these changes (if proposed and finalized in the future) would apply to ESRD facilities treating pediatric dialysis patients. In addition to any other input the public wants to provide regarding the cost reports, we are requesting responses to the following questions.

- What degree of specificity is needed in the reporting of pediatric dialysis costs?
- Are there dialysis supply costs associated with the treatment of pediatric patients that cannot be reported currently on the cost reports? If so, please specify.
- For ESRD facilities that administer dialysis to both adult and pediatric patients:

++ To what extent can ESRD facilities differentiate dialysis supply costs for adult versus pediatric patients?

—Are there specific high-cost supplies unique to the treatment of pediatric patients that could be used to isolate additional costs related to pediatric dialysis?

—When differentiating pediatric dialysis supply costs on the cost reports, would providers prefer that the cost reports include additional specific items for pediatric supplies or a separate section for supply costs associated with pediatric dialysis?

++ To what extent can providers differentiate dialysis labor costs for adult versus pediatric patients?

- Are there potential revisions that could be made to the cost report, other than those described above, that would help identify costs unique to the pediatric population (for example, revisions to items and services being reported; format revisions to help facilitate reporting on pediatric costs)?
- What obstacles do providers face in reporting pediatric specific costs of dialysis treatment? How can these obstacles be overcome?
- Pediatric dialysis patients comprise a small number of patients in ESRD facilities other than children's hospitals or medical centers. How can pediatric dialysis costs be reported in non-specialized ESRD facilities that predominantly serve adult patients without undue burden on the provider?

I. Modifying Site of Services Provided to Medicare Beneficiaries With Acute Kidney Injury (AKI)

1. Background on Medicare Payment for AKI

On June 29, 2015, the TPEA was enacted. In the TPEA, Congress amended the Act to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with 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 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 may be adjusted by the Secretary 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. In CY 2017 ESRD PPS final rule (81 FR 77870 through 77872), we finalized the AKI dialysis payment rate.

2. Current Issues and Stakeholder Concerns

Over the years, we have received several comments, including concerns from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses regarding the site of renal dialysis services for Medicare beneficiaries with AKI. A patient advocacy organization supported the proposal in the CY 2017 ESRD PPS proposed rule to adjust the AKI payment rate by only the geographic and wage indices, and stated that some patients with AKI can safely dialyze at home and have their urine and blood tests performed for the assessment of kidney function in a location closer to home. The organization recommended that home training be paid separately, without dollars removed from the base rate. In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order 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). We interpreted section 1834(r)(1) of the Act to mean the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for such year under the ESRD 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 and finalized a CY 2021 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as $253.13 (85 FR 71399).

In the CY 2017 ESRD PPS final rule, we stated that we do not expect that AKI beneficiaries will dialyze at home (81 FR 77871). We affirmed in the CY 2017 ESRD PPS final rule that payment will only be made for in-center peritoneal dialysis or hemodialysis treatments for AKI beneficiaries. CMS also stated in the CY 2017 ESRD PPS final rule that we would monitor this policy to determine if changes are necessary in the future, understanding that there may be a subset of patients for whom AKI dialysis at home is an appropriate treatment. Currently, CMS continues to believe that this population requires close medical supervision by qualified staff during their dialysis treatment.

Due to the COVID–19 PHE and an increase in the number of hospitalized patients with AKI receiving peritoneal dialysis, stakeholders have raised concerns about patients with AKI having to both travel to, and be present in, an ESRD facility post hospitalization. CMS received comments that patients with AKI require more vigilant monitoring, particularly in infection prevention, blood pressure

management, more frequent laboratory testing, additional medication administration and increased educational needs. Commenters stated that patients with AKI are distinct from regular patients with ESRD in that they need specific critical treatment. CMS continued to receive comments in response to the CY 2021 ESRD PPS proposed rule regarding this concern, including the recommendation that CMS allow patients with AKI to be dialyzed at home. Specifically, the commenters requested that CMS allow patients with AKI to pursue peritoneal dialysis in the home if the patient and nephrologist agree it is safe to do so and the home setting is the patient's choice. We also received comments from organizations requesting that CMS remove barriers that make it difficult for patients who want to select home dialysis. They specifically requested that, for the duration of the COVID–19 PHE, CMS waive the requirement that health care providers are paid for providing care to patients with AKI only when they receive in-center hemodialysis.

The 2020 TEP included a session on AKI and the current Medicare payment system. The panelists discussed cost and utilization of AKI related dialysis services since the policy change in 2017, including the incorporation of payment for dialysis treatment for patients with AKI into the ESRD PPS, assessment of the accuracy of the reported data and the effectiveness of the current AKI payment parameters for accurately capturing the costs of this population.

Panelists agreed that some patients with AKI could benefit from different treatment regimens. In particular, they noted that more frequent, gentler dialysis would be a viable option for some patients, possibly preventing hypotension. During the COVID–19 PHE, many patients received acute peritoneal dialysis treatments in the hospital upon developing AKI, and panelists expressed support for allowing patients with AKI to continue receiving acute peritoneal dialysis once they are discharged from the hospital. One panelist noted that their hospital tries to get patients with AKI accustomed to a more standard treatment regimen such as three treatments per week before discharging them to an ESRD facility. Another panelist expressed support for the implementation of transitional care units, noting they would help patients new to dialysis adjust to dialysis and the lifestyle changes that accompany it. Panelists also advocated for allowing patients with AKI to be treated at home, especially in light of the COVID–19 PHE.

Members of the TEP commented on the similar treatment frequencies observed for patients with AKI and ESRD, stating that the payment system is currently constructed to facilitate the observed treatment patterns for patients with AKI. Panelists stressed that the payment system should continue to be flexible in terms of number of treatments for patients with AKI so that those who need more frequent treatments are not impeded from receiving them.

Panelists expressed support for the CMS guidance temporarily allowing dialysis facilities to send dialysis facility staff to furnish 72x dialysis to their patients in nursing homes, from both a cost and patient health perspective. (See *https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf.*) Panelists noted that it was more efficient to send ESRD facility staff to the skilled nursing facilities rather than the costly routine and ambulance-required transportation and physical isolation expenses incurred during the public health emergency. Panelists stated that the full spectrum of care provided in the SNF setting is invaluable, particularly for the patients with multiple comorbidities.

Panelists commented on the costs per treatment observed for patients with AKI, expressing that the higher observed costs compared to ESRD treatments aligns with their expectations. Members of the panel noted that patients with AKI receive more laboratory tests to monitor for recovery, but typically are not prescribed calcimimetics or ESAs. Some panelists also noted that due to the very small population size of Medicare beneficiaries with AKI, reporting AKI costs and statistics on cost reports at a granular level introduces an outsized reporting burden on the part of the providers.

Overall, panelists expressed that the current AKI payment structure is effective and benefits both patients and facilities. One panelist pointed out that the AKI policy change, which we implemented in the CY 2017 ESRD PPS final rule (81 FR 77866 through 77872), helps hospitals, as they can send patients with AKI requiring dialysis to ESRD facilities and consequently free up capacity at the hospital.

4. Request for Information on Modifying the Site of Services Provided to Medicare Beneficiaries With AKI

CMS is soliciting feedback from the public on the differences in care for patients with AKI versus patients with ESRD and whether it has bearing on the ability of patients with AKI to perform home dialysis safely. We request any additional comments regarding potentially modifying site of renal dialysis services and payment for AKI in the home setting.

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 are soliciting 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 proposed rule, we are proposing changes to the regulatory text for the ETC Model. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed 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 purpose of the 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.[304] 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 provide 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 this 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 this 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 this proposed rule, we are updating 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 x 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 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 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 proposed rule, we are proposing 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 announce an extension of EQRS reporting requirements for facilities due to systems issues. However, we believe that none of the policies proposed in this proposed rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. We are not proposing 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

[304] *https://www.bls.gov/oes/current/oes292098.htm.* Accessed on June 7, 2021.

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 this 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. There are 229 data elements for 532,931 patients across 7,610 facilities. At 2.5 minutes per element, this yields approximately 668.21 hours per facility. Therefore, the PY 2024 burden is 5,085,050 hours (668.21 hours × 7,610 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. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Economic Analyses

A. Regulatory 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). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under 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

This rule proposes a number of routine updates to the ESRD PPS for CY 2022. The proposed 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 proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2022 for renal dialysis services furnished to ESRD beneficiaries.

b. AKI

This rule also proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would 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

This proposed rule proposes to implement requirements for the ESRD QIP, including a proposal to adopt a measure suppression policy and to suppress several ESRD QIP measures under that proposed measure suppression policy, proposals regarding the scoring methodology and payment reductions for the PY 2022 ESRD QIP, a proposed update to the SHR measure, and a proposed update to the PY 2024 performance standards. This proposed rule also includes a request for public comment on closing the gap in health equity, as well as a request for public comment on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard.

d. ETC Model

Beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. One of CMS' goals in designing the ETC Model is to test ways to incentivize home dialysis and kidney transplants, to enhance beneficiary choice of modality for renal replacement therapy, and improve quality of care and quality of life while reducing Medicare program expenditures. The substantially higher expenditures, mortality, and hospitalization rates for dialysis patients in the U.S. compared to those for individuals with ESRD in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. This proposed rule would 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 proposed changes. Notwithstanding the proposed 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 beneficiaries, along with their families and caregivers, to choose the optimal kidney replacement modality.

As noted in section IV.B of the Specialty Care Models final rule (85 FR 61264), Medicare payment rules and a deficit in beneficiary education result in a bias toward in-center hemodialysis, which is often not preferred by patients or physicians relative to home dialysis or kidney transplantation. We provided evidence from the published literature

to support the projection that higher rates of home dialysis and kidney transplants would likely reduce Medicare expenditures, and, not only enhance beneficiary choice, independence, and quality of life, but also preserve or enhance the quality of care for ESRD beneficiaries.

As described in detail in section V of this proposed rule, we believe it is necessary to propose certain changes to the ETC Model. Under the proposed changes to the ETC Model, ETC Participants would continue to receive adjusted payments but beginning for MY3, certain aspects of the ETC Model that determine those payment adjustments would change. The proposed change to the achievement benchmarking methodology is necessary to the ETC Model as this change maintains the ETC Model's expectation of savings. The proposed changes to the transplant rate, the achievement benchmarking methodology, and the improvement benchmarking and scoring methodology are necessary to increase accuracy and fairness of performance assessment. The proposed changes to the home dialysis rate, data sharing, and kidney disease patient education services waivers are necessary to support ETC Participants operating in the ETC Model.

3. Overall Impact

a. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately $140 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.

b. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately $1 million in payments to ESRD facilities in CY 2022.

c. 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, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study), the NHSN validation study, and EQRS reporting. As discussed in section IV.C and section IV.D of this proposed rule, we are proposing 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 announce an extension of EQRS reporting requirements for facilities due to systems issues. However, we believe that none of the policies proposed in this proposed rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period.

We also updated the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $215 million in information collection burden, which includes the cost of complying with this rule, and an additional $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 proposed in this proposed rule.

d. ETC Model

We estimate that the proposed changes to the ETC Model would increase the Model's projected direct savings from payment adjustments alone by $7 million over the duration of the Model. We estimate that the Model would generate $38 million in direct savings related to payment adjustments over 6.5 years with the proposed changes, and would generate $31 million in savings in the absence of the proposed changes.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule or 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 last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is 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 proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is $692.13 (6.25 hours × $110.74). Therefore, we estimate that the total cost of reviewing this regulation is $ 78,903 ($692.13 × 114).

B. Detailed Economic Analysis

1. CY 2021 End-Stage Renal Disease Prospective Payment System

a. 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 proposed 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 proposed rule. Table 9 shows the impact of the estimated CY 2022 ESRD PPS

payments compared to estimated payments to ESRD facilities in CY 2021.

TABLE 9: Impact of Proposed Changes in Payments to ESRD Facilities for CY 2022 ESRD PPS Proposed Rule

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 Payment Rate Update (E)	Effect of Total 2022 Proposed Changes (F)
All Facilities	7,717	43.4	0.2%	0.0%	1.0%	1.2%
Type						
Freestanding	7,339	41.7	0.2%	0.0%	1.0%	1.2%
Hospital based	378	1.7	0.4%	-0.1%	1.0%	1.3%
Ownership Type						
Large dialysis organization	5,886	33.6	0.2%	0.0%	1.0%	1.2%
Regional chain	887	5.3	0.3%	0.1%	1.0%	1.4%
Independent	515	2.8	0.3%	-0.1%	1.0%	1.1%
Hospital based[1]	378	1.7	0.4%	-0.1%	1.0%	1.3%
Unknown	51	0.0	0.2%	0.2%	1.0%	1.4%
Geographic Location						
Rural	1,268	6.3	0.2%	0.0%	1.0%	1.2%
Urban	6,449	37.1	0.2%	0.0%	1.0%	1.2%
Census Region						
East North Central	1,213	5.6	0.2%	-0.1%	1.0%	1.1%
East South Central	609	3.2	0.3%	-0.6%	1.0%	0.7%
Middle Atlantic	859	5.1	0.3%	-0.2%	1.0%	1.1%
Mountain	428	2.3	0.1%	-0.1%	1.0%	1.1%
New England	201	1.3	0.2%	-0.5%	1.0%	0.6%
Pacific[2]	955	6.3	0.2%	0.5%	1.0%	1.6%
Puerto Rico and Virgin Islands	52	0.3	0.2%	-0.7%	1.0%	0.4%
South Atlantic	1,794	10.4	0.2%	0.3%	1.0%	1.6%
West North Central	503	2.3	0.2%	0.1%	1.0%	1.3%
West South Central	1,103	6.5	0.2%	-0.3%	1.0%	0.9%
Facility Size						
Less than 4,000 treatments	1,248	2.4	0.2%	0.0%	1.0%	1.1%
4,000 to 9,999 treatments	2,905	11.9	0.2%	0.0%	1.0%	1.2%
10,000 or more treatments	3,384	28.9	0.2%	0.0%	1.0%	1.2%
Unknown	180	0.2	0.2%	-0.2%	1.0%	1.0%
Percentage of Pediatric Patients						

BILLING CODE 4120–01–C

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.1.c of this proposed rule is shown in column C. For CY 2022, the impact on all ESRD facilities as a result of the proposed changes to the outlier payment policy would be a 0.2 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 proposed 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 proposed 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 proposed CY 2022 ESRD PPS payment rate update as described in section II.B.1.a of this proposed rule. The proposed ESRD PPS payment rate update is 1.0 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2022 of 1.6 percent and the proposed productivity adjustment of 0.6 percent.

Column F reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed updated wage index, and the payment rate update. We expect that overall ESRD facilities would experience a 1.2 percent increase in estimated payments in CY 2022. The categories of types of facilities in the impact table show impacts ranging from a 0.4 percent increase to a 1.6 percent increase in their CY 2022 estimated payments.

b. 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 proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2022 would be approximately $8.9 billion. This estimate takes into account a projected decrease in fee-for-service Medicare dialysis beneficiary enrollment of 5.9 percent in CY 2022.

d. 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 1.2 percent overall increase in the proposed CY 2022 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.2 percent in CY 2022, which translates to approximately $30 million.

e. 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 proposed 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.

2. Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. 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 proposed 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 proposed updates to the AKI payment amount are described in section III.B of this proposed 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.

BILLING CODE 4120–01–P

TABLE 10: Impact of Proposed Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2022 ESRD PPS Proposed Rule

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of 2022 Changes in Wage Index (C)	Effect of 2022 Payment Rate Update (D)	Effect of Total 2022 Proposed Changes (E)
All Facilities	5,247	306.3	0.0%	1.0%	1.0%
Type					
Freestanding	5,125	301.1	0.0%	1.0%	1.0%
Hospital based	122	5.2	0.1%	1.0%	1.1%
Ownership Type					
Large dialysis organization	4,332	256.0	0.0%	1.0%	1.0%
Regional chain	576	31.6	0.1%	1.0%	1.1%
Independent	206	13.3	0.0%	1.0%	1.0%
Hospital based[1]	122	5.2	0.1%	1.0%	1.1%
Unknown	11	0.2	0.3%	1.0%	1.3%
Geographic Location					
Rural	868	48.3	0.0%	1.0%	1.0%
Urban	4,379	258.0	0.0%	1.0%	1.0%
Census Region					
East North Central	881	55.1	-0.2%	1.0%	0.8%
East South Central	425	22.5	-0.5%	1.0%	0.5%
Middle Atlantic	587	33.1	-0.3%	1.0%	0.7%
Mountain	303	18.8	-0.2%	1.0%	0.8%
New England	141	6.4	-0.7%	1.0%	0.3%
Pacific[2]	646	47.5	0.6%	1.0%	1.6%
Puerto Rico and Virgin Islands	3	0.0	0.0%	1.0%	1.0%
South Atlantic	1,236	74.5	0.2%	1.0%	1.2%
West North Central	340	16.0	0.1%	1.0%	1.1%
West South Central	685	32.4	-0.3%	1.0%	0.7%

Facility Size					
Less than 4,000 treatments	643	28.8	-0.1%	1.0%	0.9%
4,000 to 9,999 treatments	2,011	108.4	0.0%	1.0%	1.0%
10,000 or more treatments	2,525	167.2	0.0%	1.0%	1.0%
Unknown	68	1.9	0.0%	1.0%	1.0%
Percentage of Pediatric Patients					
Less than 2%	5,247	306.3	0.0%	1.0%	1.0%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	0	0.0	0.0%	0.0%	0.0%

[1]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
This information should not be deleted.

BILLING CODE 4120–01–C

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the proposed CY 2022 wage indices. Column D shows the effect of the proposed CY 2022 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.0 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2022 of 1.6 percent and the proposed productivity adjustment of 0.6 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 would experience a 1.0 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 1.6 percent in their CY 2022 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we propose to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $52 million would 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.

d. 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 would 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 would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. 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 would be 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 would assist us in developing knowledgeable, data-driven proposals.

3. 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 proposing to codify special scoring policies for PY 2022 at 42 CFR 413.178(h). Under these proposed regulations, we would calculate measure rates for all measures but would not calculate achievement and improvement points for any measures. We would also not calculate or award a TPS for any facility. Finally, we would not reduce payment to any facility for PY 2022.

If these policies are finalized as proposed, we believe there will be no effects of the PY 2022 ESRD QIP on ESRD Facilities, as 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 7,610 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.4 percent or 1,799 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). If our proposals are finalized as proposed, the total estimated payment reductions for all the 1,799 facilities expected to receive a payment reduction in PY 2024 would decrease from $18,247,083.76 to approximately $17,154,657.12. 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%	5,570	75.59%
0.5%	1,343	18.22%
1.0%	363	4.93%
1.5%	71	0.96%
2.0%	22	0.30%

*241 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 proposed in this proposed 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 proposals outlined in sections IV.E and IV.F of this proposed 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.

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	7,610	44.8	7,369	1,799	-0.16%
Facility Type:	7,224	43.1	7,024	1,691	-0.15%
Freestanding					
Hospital-based	386	1.8	345	108	-0.26%
Ownership Type:	5,809	34.8	5,686	1,200	-0.12%
Large Dialysis					
Regional Chain	944	5.7	921	268	-0.20%
Independent	534	2.9	491	240	-0.38%
Hospital-based (non-chain)	299	1.3	264	89	-0.29%
Unknown	24	0.0	7	2	-0.21%
Facility Size:	6,753	40.6	6,607	1,468	-0.13%
Large Entities					
Small Entities[1]	833	4.3	755	329	-0.35%
Unknown	24	0.0	7	2	-0.21%
Rural Status:	1,292	6.5	1,237	203	-0.09%
1) Yes					
2) No	6,318	38.4	6,132	1,596	-0.17%
Census Region:	1,046	6.7	1,000	261	-0.16%
Northeast					
Midwest	1,734	8.3	1,663	431	-0.18%
South	3,452	20.6	3,364	909	-0.17%
West	1,318	8.7	1,283	165	-0.08%
US Territories[2]	60	0.4	59	33	-0.36%
Census Division:	8	0.1	8	4	-0.37%
Unknown					
East North Central	1,220	6.0	1,171	355	-0.21%
East South Central	604	3.3	592	135	-0.13%
Middle Atlantic	845	5.4	806	227	-0.17%
Mountain	419	2.4	405	52	-0.08%
New England	201	1.4	194	34	-0.10%
Pacific	899	6.3	878	113	-0.08%
South Atlantic	1,746	10.7	1,700	494	-0.19%
West North Central	514	2.3	492	76	-0.10%
West South Central	1,102	6.7	1,072	280	-0.17%
US Territories[2]	52	0.3	51	29	-0.36%
Facility Size (# of total treatments)	1,315	2.6	1,195	265	-0.17%
Less than 4,000 treatments					
4,000-9,999 treatments	2,803	12.2	2,771	555	-0.13%
Over 10,000 treatments	3,246	29.7	3,240	947	-0.17%
Unknown	246	0.3	163	32	-0.18%

[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.

c. Effects of the PY 2025 ESRD QIP on ESRD Facilities

For the PY 2025 ESRD QIP, we estimate that, of the 7,610 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.4 percent or 1,799 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 1,799 facilities expected to receive a

payment reduction is approximately $17,154,657.121. 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%	5,570	75.59%
0.5%	1,343	18.22%
1.0%	363	4.93%
1.5%	71	0.96%
2.0%	22	0.30%

*Note: 241 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 proposed 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 proposed 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 proposing to use for the PY 2025

ESRD QIP, the actual impact of the PY 2025 ESRD QIP may vary significantly from the values provided here.

BILLING CODE 4120–01–P

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	7,610	44.8	7,369	1,799	-0.16%
Facility Type:	7,224	43.1	7,024	1,691	-0.15%
Freestanding					
Hospital-based	386	1.8	345	108	-0.26%
Ownership Type:	5,809	34.8	5,686	1,200	-0.12%
Large Dialysis					
Regional Chain	944	5.7	921	268	-0.20%
Independent	534	2.9	491	240	-0.38%
Hospital-based (non-chain)	299	1.3	264	89	-0.29%
Unknown	24	0.0	7	2	-0.21%
Facility Size:	6,753	40.6	6,607	1,468	-0.13%
Large Entities					
Small Entities[1]	833	4.3	755	329	-0.35%
Unknown	24	0.0	7	2	-0.21%
Rural Status:	1,292	6.5	1,237	203	-0.09%
1) Yes					
2) No	6,318	38.4	6,132	1,596	-0.17%
Census Region:	1,046	6.7	1,000	261	-0.16%
Northeast					
Midwest	1,734	8.3	1,663	431	-0.18%
South	3,452	20.6	3,364	909	-0.17%
West	1,318	8.7	1,283	165	-0.08%
US Territories[2]	60	0.4	59	33	-0.36%
Census Division:	8	0.1	8	4	-0.37%
Unknown					
East North Central	1,220	6.0	1,171	355	-0.21%
East South Central	604	3.3	592	135	-0.13%
Middle Atlantic	845	5.4	806	227	-0.17%
Mountain	419	2.4	405	52	-0.08%
New England	201	1.4	194	34	-0.10%
Pacific	899	6.3	878	113	-0.08%
South Atlantic	1,746	10.7	1,700	494	-0.19%
West North Central	514	2.3	492	76	-0.10%
West South Central	1,102	6.7	1,072	280	-0.17%
US Territories[2]	52	0.3	51	29	-0.36%
Facility Size (# of total treatments)	1,315	2.6	1,195	265	-0.17%
Less than 4,000 treatments					
4,000-9,999 treatments	2,803	12.2	2,771	555	-0.13%
Over 10,000 treatments	3,246	29.7	3,240	947	-0.17%
Unknown	246	0.3	163	32	-0.18%

[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.

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 $17,154,657.12 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 PY 2022 scoring and payment proposals as described in section IV.D of this proposed rule.

TABLE 17: Estimated Payment Reductions Payment Years 2018 through 2025

Payment year	Estimated payment reductions
PY 2025	$17,154,657
PY 2024	$17,154,657
PY 2023	$15,770,179 (85 FR 71483)
PY 2022	N/A
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)

BILLING CODE 4120–01–C

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 proposed rule, we are proposing a special rule to modify the scoring methodology such that no facility would receive a payment reduction for PY 2022. Under this special rule for PY 2022, we would calculate measure rates for all measures for that payment year, but would 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 proposed rule. This approach would help to ensure that a facility would not be penalized due to extraordinary circumstances beyond the facility's control.

4. 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 proposed in this proposed rule (discussed in detail in section V.B of this proposed rule) would 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 transplantation through financial incentives. The HDPA is an upward payment adjustment on certain home dialysis claims for ESRD facilities, as described in §§ 512.340 and 512.350, and to certain home dialysis-related claims for Managing Clinicians, as described 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 §§ 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 ETC Model. We will assess each ETC Participant's home dialysis rate, as described in § 512.365(b), and transplant rate, as described in § 512.365(c), for each MY. The ETC Participant's transplant 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 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 these benchmarks over time through subsequent notice and comment

rulemaking. In this proposed rule, the changes listed with bullets are being proposed for MY3 (beginning January 1, 2022) through the final MY of ETC Model (MY10). More detail on these changes is provided in section V.B of this proposed rule. The proposed changes that are most likely to affect the impact estimate for the ETC Model are:

- 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.
- Exclude beneficiaries with a diagnosis of and who are receiving chemotherapy or radiation for vital solid organ cancer from the transplant rate calculation.
- 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 significant increase in the rate of 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.

The ETC Model is not a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they would in the absence of the Model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the proposed changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the proposed changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years 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.

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 has not proposed 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 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 proposed in this proposed rule. For Managing Clinicians, the proposed 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. The proposed revision for the numerator of the home dialysis rate for ESRD facilities varied if the facility was owned in whole or in part by an ETC LDO, as identified by ownership information for the associated CCN. If the CCN had facilities owned by an ETC LDO, then the proposed numerator for the home dialysis rate was the home dialysis beneficiary months + 0.5*(in-center self-dialysis beneficiary months); therefore, not including nocturnal in-center dialysis months from the numerator. Otherwise, if the CCN did not have facilities owned by an ETC LDO, then the numerator was the same as described above for Managing Clinicians, such that the numerator for the home dialysis rate was home dialysis beneficiary months + 0.5*(in-center self-dialysis beneficiary months) + 0.5*(nocturnal in-center dialysis beneficiary months).

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 would have a one percent chance of receiving an increased achievement score due to this policy proposal.

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.

Beginning for MY3 and beyond, the achievement benchmarking methodology had two proposed 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 in section IV.C.2.b(3) of the Specialty Care Models final rule (85 FR 61353), which would have involved updating benchmarks based on emerging trends over the most recent experience periods for which data were available.

Second, in this proposed rule, we proposed to incorporate 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 the socioeconomic status proxies.

Third, a Health Equity Incentive was proposed for 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 5 percent, then the participant received a 0.5 point increase on their improvement score, allowing for a maximum of 2.0 total points.

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 proposed 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).[305]. 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 proposed 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 proposed rule.

No changes were proposed to the payment structure for the HDPA calculation described 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 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 Proposed Benchmark Updates

[305] UNOS. 2021. COVID–19 and Solid Organ Transplants. Transplant and Waitlist Data Visualizations. *https://unos.org/covid/*.

BILLING CODE 4120–01–P

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	14	8	-3	-12	-14	-21	-11	**-38**
Overall PPA Net & HDPA	13	6	-5	-14	-17	-24	-14	**-53**
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-4	-2	-14
Clinician PPA Upward Adjustment		0	1	1	1	1	1	5
Clinician PPA Net		0	-1	-1	-2	-2	-1	-9
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-21	-26	-32	-40	-22	-149
Facility Upward Adjustment		5	11	14	17	18	9	75
Facility PPA Net		-3	-10	-12	-15	-22	-12	-74
Facility HDPA	13	10	6					29
Total PPA Downward Adjustment		-9	-23	-29	-35	-44	-24	-163
Total PPA Upward Adjustment		6	12	15	18	19	10	80
Total PPA Net		-4	-11	-14	-17	-24	-14	-83
Total HDPA	13	10	6					29
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 Baseline (Rounded $M)

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	4.5 Year Total*
Net Impact to Medicare Spending			-2	-2	0	-1	-1	-7
Overall PPA Net & HDPA			-2	-2	0	-1	-1	-7
Total PPA Downward Adjustment			-1	0	3	4	2	8
Total PPA Upward Adjustment			-1	-2	-3	-5	-3	-15
Total PPA Net			-2	-2	0	-1	-1	-7
Total HDPA			0					0

* Model changes proposed 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 E1 for additional footnotes.

BILLING CODE 4120–01–C

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 $53 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 $38 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 proposed in this proposed rule for years 2023 going forward by calculating the difference from our final estimates in Table 18 less totals from our current baseline estimates that used the same years of data, but without the model changes applied. To clarify, the baseline 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 proposed rule used the most recent data available, from CYs 2018 and 2019. There was no impact reported in years 2021 and 2022 since the proposed payment adjustments were not effective until MY3. In addition, the proposed 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 proposed changes had a very small effect on Medicare savings; only $7 million in savings for the net impact to Medicare spending over the 4.5-year period can be attributed to the changes proposed in this 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 $74 million over the period from July 1, 2022 through June 30, 2027. In comparison, the net effect of the Clinician PPA was only $9 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 proposed rule, we are modeling a preset benchmark growth rate as proposed 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 consolidated ESRD facility or Managing Clinician'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.

Consolidated ESRD facilities at the HRR level or Managing Clinicians 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.

(a) 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 compare 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 $117 million in savings and $3 million in losses (encompassing the mean estimate of $53 million in savings in Table 18). The overall uncertainty of the impact of the model is further illustrated in Table 18, the change from baseline, where the mean $7 million dollars in savings reported for the Overall PPA Net & HDPA has $83 million in savings and $75 million in losses, for the top 10th and 90th percentiles, respectively.

(4) Effects on the Home Dialysis Rate

This proposed rule proposes to modify 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. The proposed modification was different for ESRD facilities with an aggregation group that had facilities owned by an ETC LDO, for which the nocturnal dialysis months were not included in the numerator.

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 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 nocturnal dialysis (that is, a nocturnal dialysis claims line instruction became effective in 2017) result in these proposed modifications having an insignificant impact on the savings to Medicare.

Two of the changes proposed in this proposed rule have 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. First, we proposed two strata for the achievement and improvement benchmarking based on a 50 percent cutpoint for the proportion of attributed beneficiaries with dual eligibility status or receipt of the LIS. This proposed modification would allow participants to be compared to participants who serve ESRD patients with a similar socioeconomic status, essentially making the comparison groups fairer and potentially increasing the cost to Medicare. Second, the proposed Health Equity Incentive rewarded participants with 0.5 points to their improvement score who demonstrated a sufficiently significant improvement on the home dialysis rate among their attributed beneficiaries who are dual eligible or receive the LIS.

Furthermore, we modeled the home dialysis rate achievement and improvement benchmarks by incrementally increasing every two measurement periods the benchmarks by 10 percent relative to ESRD facilities and Managing Clinicians not selected for participation. Applying the preset benchmarks update method balanced out the negative impact to Medicare savings generated from stratification and the Health Equity Incentive, essentially preserving the overall savings level reported in the Specialty Care Models final rule.

(5) 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 proposed in this proposed rule do not impact our decision in the previous 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 [306] reported 22,393 kidney transplants in 2018 compared to a kidney transplant waiting list [307] 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.

(6) Effects of the Transplant Waitlist Rate

This proposed rule includes the transplant waitlist rate described in the Specialty Care Models final rule (§ 512.365) with the following proposed modifications. First, we are proposing to exclude Medicare beneficiaries with a diagnosis of and treatment with chemotherapy or radiation for vital solid organ cancers. In our analysis of beneficiaries' eligible for the ETC Model, we found that less than 1 percent of the beneficiaries had claims for any vital solid organ cancers. Therefore, the effect of this proposed exclusion criterion is to make the beneficiaries included in the calculation of the transplant rate an improved representation of beneficiaries who are able to join the transplant waitlist and/or receive pre-emptive living donor kidney transplantation. But, due to the very low number of ETC Model potential beneficiaries with these types of cancer, the exclusion criterion is unlikely to have any significant impact on the transplant waitlist rate.

Two of the changes proposed in this proposed rule have the potential to generate higher scores for a limited subset of health care providers and therefore a small negative impact on estimated savings for the model. First, we proposed two strata for the achievement and improvement benchmarking based on a 50 percent cutpoint for the proportion of attributed beneficiaries with dual eligibility status or receipt of the LIS. This proposed modification allowed participants to be compared to participants who serve ESRD patients with a similar socioeconomic status, essentially making the comparison groups fairer and potentially increasing the cost to Medicare. Second, the proposed Health Equity Incentive rewarded participants with 0.5 points to their improvement score who demonstrated a sufficiently significant improvement on the transplant rate among their attributed beneficiaries who are dual eligible or receive the LIS.

Furthermore, we proposed to modify the transplant waitlist rate achievement and improvement benchmarks by incrementally increasing the benchmarks every two measurement periods by 10 percent relative to ESRD facilities and Managing Clinicians not selected for participation. Applying the preset benchmarks update method balanced out the negative impact to Medicare savings generated from the proposed stratification and the Health Equity Incentive, roughly preserving the overall savings level estimated at baseline for the model parameters previously finalized before the changes offered in this proposed rule.

(7) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes in this proposed 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 61355).

b. Effects on Medicare Beneficiaries

The changes in this 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 changes could also marginally improve take-up of the in-center nocturnal dialysis treatment modality compared to how the model was finalized previously since these dialysis methods were not directly incentivized (that is, accounted for in the home dialysis rate and in-center self dialysis rate numerator) in the Specialty Care Models final rule.

As previously 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 would 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 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 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.

c. Alternatives Considered

Throughout this proposed rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and the rationale for each of our policies.

This proposed rule addresses a model specific to ESRD. It provides descriptions of the requirements that we would waive, identifies the performance metrics and payment adjustments proposed to be tested, and presents rationales for our proposals, and where relevant, alternatives that we considered. We carefully considered the alternatives to this proposed 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 Model 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.

C. 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 proposed rule.

[306] United States Renal Data System. 2020. ''ADR Reference Table E6 Renal Transplants by Donor Type.'' *https://adr.usrds.org/2020/reference-tables.*

[307] Organ Procurement and Transplantation Network. 2021. ''Current US Waiting List, Overall by Organ.'' *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.*

TABLE 20: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2022)	
Category	**Transfers**
Annualized Monetized Transfers	$110 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$30 million
From Whom to Whom	Beneficiaries 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 Proposed Rule	
Category	**Transfers**
Annualized Monetized Transfers	-$1.27 million
From Whom to Whom	Federal government to ESRD facilities and Managing Clinicians

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

D. 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 an LDO, there are approximately 643 (~12 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.

TABLE 21: Revenue Table for Low Volume ESRD Facilities for CY 2022 ESRD PPS Proposed 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	643	~12%	$311	$1.26 M	$800 M

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 Large Dialysis Organizations (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 (individual 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 ETC Model, this proposed rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities and that the greater majority of ESRD facilities are not small entities. Throughout the proposed 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 would affect Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of the proposed rule would not have a significant impact on spending for a substantial number of small entities (defined as greater than 5 percent impact).

Therefore, the Secretary has determined that this proposed rule would 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. We solicit comment on the RFA analysis provided.

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 603

of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would 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 would experience an estimated 1.0 percent increase in payments.

Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. 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 proposed 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.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

G. Congressional Review Act

These proposed rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

X. 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 June 16, 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 proposes to amend 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 by revising paragraph (b)(6) 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 the definitions of ''Clinical staff'', ''Health Equity Incentive'', ''Kidney disease patient education services coinsurance patient 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.

* * * * *

ETC Large Dialysis Organization (ETC LDO) means a legal entity that owns, in whole or in part, 500 or more ESRD facilities.

* * * * *

Health Equity Incentive means the amount added to the ETC Participant's improvement score, calculated as described in § 512.370(c)(1) of this chapter, 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)) 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—

■ a. Revising paragraphs (b)(1)(ii) and (b)(2)(ii), and

■ b. Revising paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(2)(i)(A), and (c)(2)(ii)(A)(*1*) and (*2*).

The revisions 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 for ESRD facilities owned in whole or in part by an ETC LDO 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 for ESRD facilities not owned in whole or in part by an ETC LDO 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–C22.9, 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*) Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are months during which the beneficiary had a claim with any of the following procedure codes:

(*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, DF0DZZ, 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

TABLE 1 TO § 512.370(B)(1)—ETC MODEL SCHEDULE OF PPA ACHIEVMENT BENCHMARKS BY MEASUREMENT YEAR—Continued

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	Points
<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 an 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 an LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or an LIS recipient. CMS determines whether a beneficiary was dual eligible or an 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 paragraph (c)(2) of this section, is at least 5-percentage points higher than the home dialysis rate for the Benchmark Year, calculated as specified in paragraph (c)(2) of this section. 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 paragraph (c)(2) of this section, is at least 5-percentage points higher than the transplant rate for the Benchmark Year, calculated as specified in paragraph (c)(2) of this section. 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) to 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 Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations, and comply with the terms of the data sharing agreement described in paragraph (b)(1)(iv) of this section.

(iv) *Data sharing agreement.* 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-identifable 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.

(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, the ETC Participant will no longer be eligible to retrieve beneficiary-identifiable data under paragraph (b)(1)(i) of this section and 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 January 1, 2022, 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 January 1, 2022, 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).

(c)(1) Beginning 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 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 on the date the services were furnished.

(iii) The kidney disease patient education services were furnished in compliance with the applicable provisions of § 410.48 and § 512.397(b).

(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) of this part:

(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.

(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.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–14250 Filed 7–1–21; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 86 Friday,

No. 129 July 9, 2021

Part III

Securities and Exchange Commission

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change for New Rules 6.1P–O, 6.37AP–O, 6.40P–O, 6.41P–O, 6.62P–O, 6.64P–O, 6.76P–O, and 6.76AP–O and Amendments to Rules 1.1, 6.1–O, 6.1A–O, 6.37–O, 6.65A–O and 6.96–O; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92304; File No. SR–NYSEArca–2021–47]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change for New Rules 6.1P–O, 6.37AP–O, 6.40P–O, 6.41P–O, 6.62P–O, 6.64P–O, 6.76P–O, and 6.76AP–O and Amendments to Rules 1.1, 6.1–O, 6.1A–O, 6.37–O, 6.65A–O and 6.96–O

June 30, 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 June 21, 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes new Rules 6.1P–O (Applicability), 6.37AP–O (Market Maker Quotations), 6.40P–O (Pre-Trade and Activity-Based Risk Controls), 6.41P–O (Price Reasonability Checks—Orders and Quotes), 6.62P–O (Orders and Modifiers), 6.64P–O (Auction Process), 6.76P–O (Order Ranking and Display), and 6.76AP–O (Order Execution and Routing) and proposes amendments to Rules 1.1 (Definitions), 6.1–O (Applicability, Definitions and References), 6.1A–O (Definitions and References—OX), 6.37–O (Obligations of Market Makers), 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility), and 6.96–O (Operation of Routing Broker) to reflect the implementation of the Exchange's Pillar trading technology on its options market. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The Exchange plans to transition its options trading platform to its Pillar technology platform. The Exchange's and its national securities exchange affiliates' [4] (together with the Exchange, the ''NYSE Exchanges'') cash equity markets are currently operating on Pillar. For this transition, the Exchange proposes to use the same Pillar technology already in operation for its cash equity market. In doing so, the Exchange will be able to offer not only common specifications for connecting to both of its cash equity and equity options markets, but also common trading functions.

The Exchange plans to roll out the new technology platform over a period of time based on a range of symbols, anticipated for the fourth quarter of 2021. With this transition, certain rules would continue to be applicable to symbols trading on the current trading platform—the OX system,[5] but would not be applicable to symbols that have transitioned to trading on Pillar.

Instead, the Exchange proposes new rules to reflect how options would trade on the Exchange once Pillar is implemented. These proposed rule changes will (1) use Pillar terminology that is based on Exchange Rule 7–E Pillar terminology governing cash equity trading; (2) provide for common functionality on both its options and cash equity markets; and (3) introduce new functionality.

The Exchange notes that certain of the proposed new Pillar rules concern functionality not currently available on the OX system and that would be unique to how option contracts trade, and therefore would be new rules with no parallel version for the Exchange's cash equity market.

Proposed Use of ''P'' Modifier

As proposed, new rules governing options trading on Pillar would have the same numbering as current rules that address the same functionality, but with the modifier ''P'' appended to the rule number. For example, Rule 6.76–O, governing Order Ranking and Display—OX, would remain unchanged and continue to apply to any trading in symbols on the OX system. Proposed Rule 6.76P–O would govern Order Ranking and Display for trading in options symbols migrated to the Pillar platform. All other current rules that have not had a version added with a ''P'' modifier will be applicable to how trading functions on both the OX system and Pillar. Once all options symbols have migrated to the Pillar platform, the Exchange will file a separate rule proposal to delete rules that are no longer operative because they apply only to trading on the OX system.

To reflect how the ''P'' modifier would operate, the Exchange proposes to add rule text immediately following the title ''Rule 6–O Options Trading,'' and before ''Rules Principally Applicable to Trading of Option Contracts'' that would provide that rules with a ''P'' modifier would be operative for symbols that are trading on the Pillar trading platform. As further proposed, if a symbol is trading on the Pillar trading platform, a rule with the same number as a rule with a ''P'' modifier would no longer be operative for that symbol and the Exchange would announce by Trader Update [6] when symbols are trading on the Pillar trading platform.[7]

[4] The Exchange's national securities exchange affiliates are the New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE National, Inc. (''NYSE National''), and NYSE Chicago, Inc. (''NYSE Chicago'').

[5] ''OX'' refers to the Exchange's current electronic order delivery, execution, and reporting system for designated option issues through which orders and quotes of Users are consolidated for execution and/or display. *See* Rule 6.1A–O(13). ''OX Book'' refers to the OX's electronic file of orders and quotes, which contain all of the orders in each of the Display Order and Working Order processes and all of the Market Makers' quotes in the Display Order Process. *See* Rule 6.1A–O(14). With the transition to Pillar, the Exchange would no longer use the terms ''OX'' or ''OX Book'' and rules using those terms would not be applicable to trading on Pillar. Once the transition is complete, the Exchange will file a subsequent proposed rule change to delete references to OX and OX Book from the rulebook.

[6] Trader Updates are available here: *https://www.nyse.com/trader-update/history.* Anyone can subscribe to email updates of Trader Updates, available here: *https://www.nyse.com/subscriptions.*

[7] The Exchange used the same description when it transitioned its cash equity platform to Pillar. *See*

The Exchange believes that adding this explanation regarding the ''P'' modifier in Exchange rules would provide transparency regarding which rules and definitions would be operative during the symbol migration to Pillar.

Summary of Proposed Rule Changes

In this filing, the Exchange proposes the following new Pillar rules: Rules 6.1P–O (Applicability), 6.37AP–O (Market Maker Quotations), 6.40P–O (Pre-Trade and Activity-Based Risk Controls), 6.41P–O (Price Reasonability Checks—Orders and Quotes), 6.62P–O (Orders and Modifiers), 6.64P–O (Auction Process), 6.76P–O (Order Ranking and Display), and 6.76AP–O (Order Execution and Routing). The Exchange also proposes to amend Rules 1.1 (Definitions), 6.1–O (Applicability, Definitions and References), and 6.1A–O (Definitions and References—OX) to reflect definitions that would be applicable for options trading on Pillar and make conforming amendments to Rules 6.37–O (Obligations of Market Makers), 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility), and 6.96–O (Operation of Routing Broker). These proposed rules would set forth the foundation of the Exchange's options trading model on Pillar and would use existing Pillar terminology currently in effect for the Exchange's cash equity platform.

Because certain proposed rules have definitions and functions that carry forward to other proposed rules, the Exchange proposes to describe the new rules in the following order (rather than by rule number order): Definitions, applicability, ranking and display, execution and routing, orders and modifiers, market maker quotations, pre-trade and activity-based risk controls, price reasonability checks, and auctions.

To promote clarity and transparency, the Exchange further proposes to add a preamble to the following current rules specifying that they would not be applicable to trading on Pillar: Rule 6.1–O (Applicability, Definitions and References), 6.1A–O (Definitions and References—OX), Rule 6.37A–O (Market Maker Quotations), 6.40–O (Risk Limitation Mechanism), 6.60–O (Price Protection—Orders), 6.61–O (Price Protections—Quotes), 6.62–O (Certain Types of Orders Defined), 6.64–O (OX Opening Process), 6.76–O (Order Ranking and Display—OX), 6.76A–O (Order Execution—OX), 6.88–O (Directed Orders), and 6.90–O (Qualified Contingent Crosses).

As discussed in greater detail below, the Exchange is not proposing fundamentally different functionality applicable to options trading on Pillar than on the OX system. However, with Pillar, the Exchange would introduce new terminology, and as applicable, new or updated functionality that would be available for options trading on the Pillar platform.

The Exchange notes that new rules relating to electronic complex trading on Pillar will be addressed in separate proposed rule change.

Proposed Rule Changes

Rule 1.1—Definitions

Rule 1.1 sets forth definitions that are applicable to both the Exchange's cash equity and options markets. Rule 6.1–O(b) sets forth definitions that are applicable to the trading of option contracts on the Exchange. Rule 6.1A–O sets forth definitions that are applicable to trading on the Exchange's current OX system. In connection with the transition of options trading to Pillar, the Exchange proposes to copy the definitions currently set forth in Rules 6.1–O and 6.1A–O into to Rule 1.1, with changes as described below. This proposed rule change would streamline the Exchange's rules by consolidating definitions that would be applicable for trading on Pillar into Rule 1.1. Once the transition to Pillar is complete, the Exchange will file a subsequent proposed rule change to delete current Rules 6.1–O and 6.1A–O.

In connection with adding definitions to Rule 1.1, the Exchange proposes to delete the sub-paragraph numbering currently set forth in Rule 1.1. The Exchange does not believe that the sub-paragraph numbering is necessary because the definitions are organized in alphabetical order and would continue to be organized in alphabetical order. In addition, removing the sub-paragraph numbering would make any future amendments to Rule 1.1 easier to process as any new definitions would simply be added in alphabetical order.

Certain definitions in Rule 1.1 currently specify that they are only for ''equities'' trading. With the proposed consolidation of definitions, some of those definitions will become applicable to both options and cash equity trading, and others will continue to be applicable only to cash equity trading. With the proposed consolidation, the Exchange proposes to remove existing language limiting those definitions to ''equities'' traded on the Exchange if the definition would be equally applicable to options trading. In addition, to the extent that a proposed definition would continue to be applicable only to cash equity trading, the Exchange proposes to make a global change to update references to ''equities'' traded on the Exchange to ''cash equity securities'' traded on the Exchange. The Exchange believes these proposed modifications would add clarity and consistency to Exchange rules.

The Exchange proposes the following amendments to Rule 1.1.

First, definitions set forth in Rule 6.1–O(b) would be added to Rule 1.1 in alphabetical order without any substantive differences.[8] To promote clarity, if the definition that is being copied is not specifically about options trading, the Exchange proposes to add an introductory clause to the definition to specify that the term is for options traded on the Exchange. The Exchange does not propose to copy the definition of ''Quote with Size,'' which is currently defined in Rule 6.1–O(b)(33), to Rule 1.1 because that term would not be used in the Pillar rules, and does not propose to copy the definition of ''Short Term Options Series,'' because it is duplicative of Commentary .07 to Rule 6.4–O. In addition, the Exchange is not including the definition of ''Foreign Broker/Dealer,'' which is currently defined in Rule 6.1–O(b)(31), in Rule 1.1, as this term is not used anywhere else in Exchange rules.[9] The Exchange also proposes the following clarifying, non-substantive changes to definitions that are being copied from Rule 6.1–O(b) to Rule 1.1:

- The Exchange proposes to provide that the term ''class of options'' or ''class'' would mean all series of options, both puts and calls, overlying the same underlying security.
- The Exchange proposes to streamline the definitions of ''Closing

Securities Exchange Act Release Nos. 75494 (July 20, 2015), 80 FR 44170 (July 24, 2015) (SR–NYSEArca–2015–38) (Approval Order) and 74951 (May 13, 2015), 80 FR 28721 (May 19, 2015) (Notice).

[8] Rule 6.1–O(b) has definitions for: Options Clearing Corporation, Rules of the Options Clearing Corporation, Clearing Member, Participating Exchange, Option Contract, Exchange Option Transaction and Exchange Transaction, Type of Option, Call, Put, Class of Options, Series of Options, Option Issue, Underlying Stock or Underlying Security, Exercise Price, Aggregate Exercise Price, Expiration Month, Expiration Date, Long Position, Short Position, Opening Purchase Transaction, Opening Writing Transaction, Closing Sale Transaction, Closing Purchase Transaction, Covered, Uncovered, Outstanding, Primary Market, Options Trading, Customer, Trading Crowd, Foreign Broker/Dealer, Exchange-Traded Fund Share, Quote with Size, Trading Official, Non-OTP Firm or Non-OTP Holder Market Maker, Firm, Consolidated Book, Crowd Participants, Electronic Order Capture System, Short Term Option Series, and Quarterly Options Series.

[9] The Exchange is not proposing to delete the definitions of either ''Quote with Size'' or ''Foreign Broker/Dealer'' at this time as such terms would be deleted in the subsequent filing to delete Rule 6.1–O.

Purchase Transaction,'' Closing Sale Transaction,'' ''Opening Purchase Transaction,'' and ''Opening Writing Transaction'' without any substantive differences.

• The Exchange proposes to revise the definition of ''Electronic Order Capture System'' to eliminate reference to the Commission's order Instituting Public Administrative Proceedings Pursuant to Section 19(h)(1) of the Securities Exchange Act of 1934, Making Findings and Imposing Remedial Sanctions, which was the initial authority for the Exchange to specify requirements relating to the Electronic Order Capture System. The Exchange will continue to include requirements for the Electronic Order Capture System in its rules and does not believe it is necessary to continue to cite to the original authority for this requirement in Exchange rules.

• The Exchange proposes to streamline the definition of ''Expiration Date'' to eliminate now obsolete language limiting the definition to options expiring before, on, or after February 15, 2015. In addition, the Exchange does not propose to include the following text in the Rule 1.1 definition of ''Expiration Date'': ''Notwithstanding the foregoing, in the case of certain long-term options expiring on or after February 1, 2015 that the Options Clearing Corporation has designated as grandfathered, the term ''expiration date'' shall mean the Saturday immediately following the third Friday of the expiration month.'' This rule text is now obsolete as the Exchange does not have any series trading on the Exchange with such Saturday expiration dates.

• The Exchange proposes to add to the definition of ''option contract'' that option contracts would include within the definition of ''security'' or ''securities'' as such terms are used in the Bylaws and Rules of the Exchange. This proposed text is copied from the last sentence of current Rule 6.1–O(a). As described below, proposed Rule 6.1P–O would not include this text.

• The Exchange proposes to amend the definition of ''option issue'' to mean the security underlying a class of options.

• The Exchange proposes to streamline the definition of ''outstanding'' without any substantive differences.

• The Exchange proposes to use the term ''underlying security'' rather than referring separately to an ''underlying stock or Exchange-Traded Fund Share,'' as an Exchange-Traded Fund Share is a security as that term is defined in Rule 1.1 (and is also an NMS stock).

Second, definitions set forth in Rule 6.1A–O(a) would be moved and added to Rule 1.1 in alphabetical order without any substantive differences.[10] Because certain of these definitions are already set forth in Rule 1.1 for cash equity trading, the Exchange proposes to amend those existing definitions to specify that they would be applicable to options trading, and if applicable, set forth differences for options trading, as described in more detail below. The Exchange does not propose to move the definition of ''Directed Order Market Maker'' to Rule 1.1 because in Pillar, the Exchange would no longer support Directed Order Market Makers. In addition, the Exchange does not propose to move the definitions of ''Complex BBO'' or ''Complex NBBO'' to Rule 1.1, and instead will be proposing to define those terms in a separate proposed rule change relating to electronic complex trading. As noted above, the terms ''OX'' and ''OX Book'' will not be used in Pillar rules.

Finally, in addition to definitions that are being moved without any substantive changes, the Exchange proposes the following specific changes to Rule 1.1 definitions:[11]

• *Approved Person:* The Exchange proposes a non-substantive amendment to change the word ''a'' to ''an'' before ''OTP Firm.''

• *Authorized Trader:* The Exchange proposes to amend the Rule 1.1 definition of ''Authorized Trader'' to remove the limitation to equities trading so that it is applicable to both cash equity securities and options traded on the Exchange, and to add that it can mean a person who may submit orders to the Exchange's Trading Facilities on behalf of his or her OTP Holder. These proposed amendments combine the definition of Authorized Trader currently set forth in Rule 6.1A–O(a)(1) with the existing Rule 1.1 definition of Authorized Trader without any substantive differences.

• *Away Market:* The Exchange proposes to amend the Rule 1.1 definition of ''Away Market'' to add how that term would be used for options trading on the Exchange. As proposed, the new text would provide: ''[w]ith respect to options traded on the Exchange, the term ''Away Market'' means any Trading Center (1) with which the Exchange maintains an electronic linkage, and (2) that provides instantaneous responses to orders routed from the Exchange.'' This proposed definition is based on the Rule 6.1A–O(a)(12) definition of ''NOW Recipient'' with only a non-substantive difference to use the Pillar term of ''Away Market'' instead of the term ''NOW Recipient.'' The Exchange does not include in this definition reference to designating and publishing to its website certain Away Markets because such markets are by definition those with which the Exchange maintains electronic linkage (*i.e.,* pursuant to the Options Order Protection and Locked/Crossed Market Plan).

• *BBO:* The Exchange proposes to amend the Rule 1.1 definition of ''BBO'' to add how that term would be used for options trading on the Exchange. As proposed, with respect to options traded on the Exchange, BBO would mean the best displayed bid or best displayed offer on the Exchange. This definition is based on the Rule 6.1A–O(a)(2)(a) definition of BBO without any substantive differences.

• *Consolidated Book:* The term ''Consolidated Book'' is currently defined in Rule 6.1–O(b)(37) and the term ''OX Book'' is currently defined in Rule 6.1A–O(a)(14). For Pillar, the Exchange proposes to define the term ''Consolidated Book'' based on both of those existing definitions and would provide that for options traded on the Exchange, the term ''Consolidated Book'' would mean the Exchange's electronic book of orders and quotes and that all orders and quotes that are entered into the Consolidated Book would be ranked and maintained in accordance with the rules of priority, as provided for in proposed Rule 6.76P–O. This proposed definition is also similar to the existing Rule 1.1 definition of ''NYSE Arca Book,'' which would be amended to specify that the definition would only be for cash equity securities traded on the Exchange.

• *Core Trading Hours:* The definition of Core Trading Hours would be applicable to both cash equity securities and options trading on the Exchange. Because options trading may extend past 4:00 p.m., the Exchange proposes to amend the Rule 1.1 to provide that for options traded on the Exchange, transactions may be effected on the Exchange for an equity options class until close of trading of the primary market for the securities underlying an options class. This proposed text is

[10] Rule 6.1A–O(a) has definitions for: Authorized Trader, BBO, Complex BBO, Core Trading Hours, Customer, Professional Customer, Lead Market Maker, Market Center, Marketable, Market Maker, Market Maker Authorized Trader, Minimum Price Variation, NBBO, Complex NBBO, NOW Recipient, OX, OX Book, Routing Broker, Sponsored Participant, Sponsoring OTP Firm, Sponsorship Provisions, User, Directed Order Market Maker, and Order Flow Provider.

[11] The Exchange also proposes a non-substantive amendment to the definition of ''Exchange'' to add a period at the end of the sentence.

based on current Rule 6.1A–O(a)(3) without substantive changes.[12]

• *Customer and Professional Customer:* The Exchange proposes to amend Rule 1.1 to add the definitions of ''Customer'' and ''Professional Customer.'' The proposed definitions are based on the definitions of Customer and Professional Customer set forth in Rule 6.1A–O(a)(4) and (4A) with non-substantive differences only to specify that these definitions would be applicable for options traded on the Exchange, eliminate redundant headers, and re-number the sub-paragraphs. The Exchange also proposes to include a cross-reference to the definition of a broker or dealer as defined Sections 3(a)(4) and 3(a)(5) of the Exchange Act and rules thereunder.[13] The Exchange believes that this specificity adds clarity and transparency to the proposed definition.

• *Lead Market Maker:* The Exchange proposes to amend the Rule 1.1 definition of ''Lead Market Maker'' to add how that term would be used for options trading. As proposed, the new text would provide that for options traded on the Exchange, the term ''Lead Market Maker'' or ''LMM'' would ''mean a person that has been deemed qualified by the Exchange for the purpose of making transactions on the Exchange in accordance with Rule 6.82–O. Each LMM must be registered with the Exchange as a Market Maker. Any OTP Holder or OTP Firm registered as a Market Maker with the Exchange is eligible to be qualified as an LMM.'' This proposed definition is based on the Rule 6.1A–O(a)(5) definition of Lead Market Maker without any differences.

• *Marketable:* The Exchange proposes to amend the Rule 1.1 definition of ''Marketable'' to extend it to address options traded on the Exchange. The current description of the term ''Marketable'' for purposes of Market Orders is the same in both Rules 1.1 and 6.1A–O(a)(7). With respect to Limit Orders, in Rule 1.1, the term ''Marketable'' currently means an order that can be immediately executed or routed. The current Rule 6.1A–O(a)(7) definition of the term ''Marketable'' for Limit Orders means when the price of the order matches or crosses the NBBO on the other side of the market. The current Rule 1.1 definition relating to Limit Orders means substantively the same thing as the Rule 6.1A–O(a)(7) description for Limit Orders, and the Exchange proposes using the existing Rule 1.1 definition of the term ''Marketable'' for both cash equity and options trading of Limit Orders. The Exchange also proposes a non-substantive amendment to add a comma after the phrase, ''the term ''Marketable'' means'' and before ''for a Limit Order.''

• *Market Maker:* The Exchange proposes to amend the Rule 1.1 definition of ''Market Maker'' to add how that term would be used for options trading. As proposed, the new text would provide that for options traded on the Exchange, the term ''Market Maker'' would refer ''to an OTP Holder or OTP Firm that acts as a Market Maker pursuant to Rule 6.32–O.'' This proposed definition is based on the Rule 6.1A–O(a)(8) definition of Market Maker without any differences. The Exchange also proposes to include in the definition of Market Maker that for purposes of the NYSE Arca rules, the term Market Maker includes Lead Market Makers, unless the context otherwise indicates. This proposed text is based on Rule 6.1–O(c), References, without substantive differences. The Exchange believes this proposed change would streamline and clarify this definition.

• *Market Maker Authorized Trader:* The Exchange proposes to amend the Rule 1.1 definition of ''Market Maker Authorized Trader'' to add how that term would be used for options trading. As proposed, the new text would provide that for options traded on the Exchange, the term ''Market Maker Authorized Trader'' or ''MMAT'' would ''mean an authorized trader who performs market making activities pursuant to Rule 6–O on behalf of an OTP Firm or OTP Holder registered as a Market Maker.'' This proposed definition is based on the Rule 6.1A–O(a)(9) definition of Market Maker Authorized Trader without any differences.

• *Market Participant Identifier (''MPID''):* The Exchange proposes to add a new definition to Rule 1.1 for ''Market Participant Identifier ('MPID').'' This term is currently used in Rules 7.19–E and 7.31–E(i)(2). Because this term would also be used for options trading, the Exchange believes that defining this term in Rule 1.1 would promote clarity and transparency. The proposed definition would provide that ''Market Participant Identifier'' or ''MPID'' refers to the identification number(s) assigned to the orders and quotes of a single ETP Holder, OTP Holder, or OTP Firm for the execution and clearing of trades on the Exchange by that permit holder. The definition would further provide that an ETP Holder, OTP Holder, or OTP Firm may obtain multiple MPIDs and each such MPID may be associated with one or more sub-identifiers of that MPID.

• *Minimum Price Variation or MPV:* The Exchange proposes to amend Rule 1.1 to add the definition of ''Minimum Price Variation'' or ''MPV'' for both cash equity securities and options that are traded on the Exchange. The Exchange proposes that the term ''Minimum Price Variation'' or ''MPV'' means the minimum price variations established by the Exchange. The Exchange further proposes that the MPV for quoting cash equity securities traded on the Exchange are set forth in Rule 7.6–E. The Exchange further proposes that the MPV for quoting and trading options traded on the Exchange are set forth in Rule 6.72–O(a). The proposed definition as it relates to options trading is based on the Rule 6.1A–O(a)(10) definition of MPV.

• *NBBO:* The Exchange proposes to amend the Rule 1.1 definition of ''NBBO, Best Protected Bid, Best Protected Offer, Protected Best Bid and Offer (PBBO)'' to add how the term NBBO would be used for options trading. The Exchange proposes that: ''[w]ith respect to options traded on the Exchange, the term ''NBBO'' means the national best bid or offer. The terms ''NBB'' means the national best bid and ''NBO'' means the national best offer. This proposed definition is based on the Rule 6.1A–O(a)(11)(a) definition of NBBO without any differences. In addition, unless otherwise specified, for options trading, the Exchange may adjust its calculation of the NBBO based on information about orders it sends to Away Markets, execution reports received from those Away Markets, and certain orders received by the Exchange. This proposed text reflects how the Exchange currently calculates the NBBO for options trading and is based on how the PBBO is calculated on the Exchange's cash equity market, as described in Rule 7.37–E(d)(2).[14] The Exchange proposes that it would adjust its calculation of the NBBO for options traded on the Exchange in the same manner that the Exchange calculates the PBBO for cash equity securities traded on the Exchange. The Exchange further notes that there are limited circumstances when the Exchange would not adjust its calculation of the

[12] The Exchange does not propose to include text regarding trading that continues 15 minutes after the regular time set for the normal close of trading in the primary markets with respect to index options classes, as this is already addressed in Rule 5.20–O(a) (Trading Sessions).

[13] The Exchange does not propose to carry over the definition of ''Customer'' that is set forth in Rule 6.1–O(b)(29) as unnecessary.

[14] *See* Securities Exchange Act Release No. 91564 (April 14, 2021), 86 FR 20541 (April 20, 2021) (SR–NYSEArca–2021–21) (Notice of filing and immediate effectiveness of proposed rule change to specify when the Exchange may adjust its calculation of the PBBO).

NBBO, and would determine the NBBO for options in the same way that the Exchange determines the NBBO for cash equity securities traded on the Exchange. As described in detail below, the Exchange will specify in its rules when it would be not be using an adjusted NBBO for purposes of a specific rule.

The Exchange further proposes that the term ''Away Market NBBO'' would refer to a calculation of the NBBO that excludes the Exchange's BBO.

• *NYSE Arca Book:* The Exchange proposes to amend the Rule 1.1 definition of ''NYSE Arca Book'' to specify that this term is applicable only for cash equity securities traded on the Exchange. As noted above, the Exchange uses the term ''Consolidated Book'' for options traded on the Exchange.

• *NYSE Arca Marketplace:* The Exchange proposes to amend the Rule 1.1 definition of ''NYSE Arca Marketplace'' to specify that this term is applicable only for cash equity securities traded on the Exchange.

• *Order Flow Provider or OFP:* The Exchange proposes to add the definition of ''Order Flow Provider or OFP'' to Rule 1.1 to mean ''any OTP Holder that submits, as agent, orders to the Exchange.'' This proposed definition is based on the Rule 6.1A–O(a)(21) definition of ''Order Flow Provider'' without any differences.

• *Trading Center:* The Exchange proposes to amend the Rule 1.1 definition of ''Trading Center'' to add how this term would be used for options trading. As proposed: ''[w]ith respect to options traded on the Exchange, for purposes of Rule 6–O, the term ''Trading Center'' means a national securities exchange that has qualified for participation in the Options Clearing Corporation pursuant to the provisions of the rules of the Options Clearing Corporation.'' This proposed definition is based on the Rule 6.1A–O(a)(6) definition of ''Market Center'' with a non-substantive difference to use the term ''Trading Center'' instead of ''Market Center.''

• *User:* The Exchange proposes to amend the Rule 1.1 definition of ''User'' to add how this term would be used for options trading. As proposed: ''[w]ith respect to options traded on the Exchange, the term 'User' shall mean any OTP Holder or OTP Firm who is authorized to obtain access to the Exchange pursuant to Rule 6.2A–O.'' This proposed definition is based on the Rule 6.1A–O(a)(19) definition of User with non-substantive differences to use Pillar terminology.

• *User Agreement:* The Exchange proposes a non-substantive amendment to the Rule 1.1 definition of ''User Agreement'' to replace the term ''NYSE Arca, L.L.C'' with the term the ''Exchange.''

In addition to proposed amendments to Rule 1.1, the Exchange proposes to amend Rule 6.96–O to add the definition of ''Routing Broker,'' which is currently defined in Rule 6.1A–O(a)(15). For options trading on Pillar, the Exchange proposes to define the term in Rule 6.96–O (Operation of a Routing Broker) to mean ''the broker-dealer affiliate of NYSE Arca, Inc. and any other non-affiliate that provides services for routing orders submitted to the Exchange to other Trading Facilities for execution whenever such routing is required by NYSE Arca Rules and federal securities laws.'' [15] The proposed rule text is based on the current definition in Rule 6.1A–O(a)(15), with non-substantive amendments to use Pillar terminology.

In connection with the proposed amendments to Rule 1.1, the Exchange proposes to add the following preamble to Rule 6.1A–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.1A–O would not be applicable to trading on Pillar.

Proposed Rule 6.1P–O: Applicability

Current Rule 6.1–O sets forth the applicability, definitions, and references in connection with options trading. As noted above, the definitions in Rule 6.1–O(b) and reference to LMMs being included in the definition of Market Maker will be copied to proposed Rule 1.1 for purposes of trading on Pillar.

The Exchange proposes new Rule 6.1P–O to include only those portions of Rule 6.1–O relating to applicability of Exchange Rules that would continue to be applicable after the transition to Pillar. Proposed Rule 6.1P–O(a) would be based on current Rule 6.1–O(a) with differences that would streamline the proposed rule and reduce duplication of terms defined in Rule 1.1. Proposed Rule 6.1P–O(b) would be based in part on Rule 6.1–O(e) regarding the ''Applicability of Other Exchange Rules,'' with changes to eliminate obsolete and duplicative text and to clarify the proposed rule to provide that unless stated otherwise, Exchange Rules would be applicable to transactions on the Exchange in option contracts.

In connection with proposed Rule 6.1P–O, the Exchange proposes to add the following preamble to Rule 6.1–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.1–O would not be applicable to trading on Pillar.

Proposed Rule 6.76P–O: Order Ranking and Display

Rule 6.76–O governs order ranking and display for the current Exchange options trading system. Proposed Rule 6.76P–O would address order ranking and display for options trading under Pillar.

With the transition to Pillar, the Exchange does not propose any substantive differences to how orders would be ranked and displayed on the Exchange. However, the Exchange proposes to eliminate the terminology relating to the ''Display Order Process'' and ''Working Order Process'' and instead use Pillar terminology based on Rule 7.36–E, which governs order ranking and display on the Exchange's cash equity market. The Exchange proposes a difference between proposed Pillar options rules and the existing cash equity Pillar rules to reflect that, in addition to entering orders, Market Makers enter quotes on the options trading platform. Accordingly, when the cash equity rules refer to ''orders,'' the proposed options Pillar rules would refer to both ''orders and quotes.''

As discussed in detail below, the Exchange believes that the proposed new rule text provides transparency with respect to how the Exchange's price-time priority model would operate through the use of new terminology applicable to all orders and quotes on the Pillar trading platform.

Proposed Rule 6.76P–O(a) would set forth definitions for purposes of all of Rule 6–O Options Trading on the Pillar trading platform, including proposed Rule 6.76AP–O (Order Execution and Routing), described below. The proposed definitions are based on Rule 7.36–E(a) definitions for purposes of Rule 7–E cash equity trading, with differences, as noted above, to reference ''orders and quotes'' throughout proposed Rule 6.76P–O. The Exchange believes that these proposed definitions would provide transparency regarding how the Exchange would operate its options platform on Pillar, and serve as the foundation for how orders and modifiers would be described for options trading on Pillar, as discussed in more detail below.

• Proposed Rule 6.76P–O(a)(1) would define the term ''display price'' to mean the price at which an order or quote ranked Priority 2—Display Orders or

[15] The Exchange also proposes non-substantive amendments to Rule 6.96–O to renumber current paragraphs (a), (b), and (c), as paragraphs (b), (c), and (d).

Market Order is displayed, which may be different from the limit price or working price of the order. This proposed definition is based on Rule 7.36–E(a)(1). The Exchange proposes a non-substantive difference to refer to ''order or quote ranked Priority 2—Display Orders,'' versus referring to ''Limit Order,'' as set forth in Rule 7.36–E(a)(1). The term ''Priority 2—Display Orders'' is described in more detail below. The Exchange also proposes a second difference compared to the Exchange's cash equity rules to include Market Orders as interest that may have a display price (for example, as described below and consistent with current functionality, a Market Order could be displayed at its Trading Collar).

• Proposed Rule 6.76P–O(a)(2) would define the term ''limit price'' to mean the highest (lowest) specified price at which a Limit Order or quote to buy (sell) is eligible to trade. The limit price is designated by the User. As noted in the proposed definitions of display price and working price, the limit price designated by the User may differ from the price at which the order would be displayed or eligible to trade. This proposed definition is based on Rule 7.36–E(a)(2) without any substantive differences. The Exchange proposes one non-substantive difference to refer to the specified price of a ''Limit Order or quote,'' versus referring to ''Limit Order,'' as set forth in Rule 7.36–E(a)(2).

• Proposed Rule 6.76P–O(a)(3) would define the term ''working price'' to mean the price at which an order or quote is eligible to trade at any given time, which may be different from the limit price or display price of an order. This proposed definition is based on Rule 7.36–E(a)(3) without any substantive differences. The Exchange proposes one non-substantive difference to refer to ''order or quote'' for purposes of determining ranking priority. The Exchange believes that the term ''working price'' would provide clarity regarding the price at which an order may be executed at any given time. Specifically, the Exchange believes that use of the term ''working'' denotes that this is a price that is subject to change, depending on the circumstances. The Exchange will be using this term in connection with orders and modifiers, as described in more detail below.

• Proposed Rule 6.76P–O(a)(4) would define the term ''working time'' to mean the effective time sequence assigned to an order or quote for purposes of determining its priority ranking. The Exchange proposes to use the term ''working time'' in its rules for trading on the Pillar trading platform instead of terms such as ''time sequence'' or ''time priority,'' which are used in rules governing trading on the Exchange's current system. The Exchange believes that use of the term ''working'' denotes that this is a time assigned to an order for purposes of ranking and is subject to change, depending on circumstances. This proposed definition is based on Rule 7.36–E(a)(4) without any substantive differences. The Exchange proposes one non-substantive difference to refer to an ''order or quote,'' versus referring solely to ''an order,'' as set forth in Rule 7.36–E(a)(4).

• Proposed Rule 6.76P–O(a)(5) would define an ''Aggressing Order'' or ''Aggressing Quote'' to mean a buy (sell) order or quote that is or becomes marketable against sell (buy) interest on the Consolidated Book. The proposed terms would therefore refer to orders or quotes that are marketable against other orders or quotes on the Consolidated Book, such as incoming orders or quotes as well as orders that have returned unexecuted after routing. These terms would also be applicable to resting orders or quotes that become marketable due to one or more events. For the most part, resting orders or quotes will have already traded with contra-side interest against which they are marketable. To maximize the potential for orders or quotes to trade, the Exchange continually evaluates whether resting interest may become marketable. Events that could trigger a resting order to become marketable include updates to the working price of such order or quote, updates to the NBBO, changes to other interest resting on the Consolidated Book, or processing of inbound messages. To address such circumstances, the Exchange proposes to include in proposed Rule 6.76P–O(a)(5) that a resting order or quote may become an Aggressing Order or Aggressing Quote if its working price changes, if the NBBO is updated, because of changes to other orders or quotes on the Consolidated Book, or when processing inbound messages.

The proposed definition of an ''Aggressing Order'' is based on Rule 7.36–E(a)(5) without any substantive differences. The proposed rule includes non-substantive differences to account for options trading, such as including the defined term ''Aggressing Quote''; referring to an ''order or quote'' versus ''an order''; referring to the Consolidated Book rather than NYSE Arca Book; and referring to the NBBO instead of the PBBO, which is not a term used in options trading. The Exchange believes that these proposed definitions would promote transparency in Exchange rules by providing detail regarding circumstances when a resting order or quote may become marketable, and thus would be an Aggressing Order or Aggressing Quote.

Proposed Rule 6.76P–O(b) would govern the display of non-marketable Limit Orders and quotes. The proposed Pillar functionality would operate as described in current preamble of Rule 6.76–O and the Display Order Process set forth in Rule 6.76–O(a)(1), without any substantive differences, but will not use the terms ''Display Order Process,'' ''Working Order Process,'' or ''OX,'' because the Exchange is not proposing to use that terminology in Pillar. Throughout proposed paragraph (b) of Rule 6.76P–O, the Exchange proposes to use the term ''will'' in instead of ''shall.'' As proposed, the Exchange would display ''all non-marketable Limit Orders or quotes ranked Priority 2—Display Orders unless the order or modifier instruction specifies that all or a portion of the order is not to be displayed,'' which rule text is substantially identical to the first sentence of the preamble to current Rule 6.76–O except that Pillar ranking terminology would be used.

Rule 6.76P–O(b)(1), which is substantially identical to current Rule 6.76–O(b), would provide that except as otherwise permitted in proposed new Rule 6.76AP–O (discussed below), all non-marketable displayed interest would be displayed on an anonymous basis.

Proposed Rule 6.76P–O(b)(2) is substantially identical to the second sentence of the preamble to current Rule 6.76–O, and would provide that the Exchange would disseminate current consolidated quotations/last sale information, and such other market information as may be made available from time to time pursuant to agreement between the Exchange and other Market Centers, consistent with the OPRA Plan.

Finally, proposed Rule 6.76P–O(b)(3) would provide that if ''an Away Market locks or crosses the Exchange BBO, the Exchange will not change the display price of any Limit Orders or quotes ranked Priority 2—Display Orders and any such orders will be eligible to be displayed as the Exchange's BBO.'' This proposed concept, which is based on Rule 7.36–E(b)(4) (but omits the cash equity-related information regarding regulatory halts), ensures that resting displayed interest that did not cause a locked or crossed market condition can stand their ground and maintain priority at the price at which they were originally displayed. This provision is consistent with the treatment of displayed orders on the Exchange's cash

equity market as described in Rule 7.36–E(b)(4).

Proposed Rule 6.76P–O(c) would describe the Exchange's general process for ranking orders and quotes and would be comparable to Rule 6.76–O(a), without any substantive differences. As proposed, Rule 6.76P–O(c) would provide that all non-marketable orders and quotes would be ranked and maintained in the Consolidated Book according to price-time priority in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order/quote or modifier condition. Accordingly, orders and quotes would be first ranked by price. Next, at each price level, orders and quotes would be assigned a priority category. Orders and quotes in each priority category would be required to be exhausted before moving to the next priority category. Within each priority category, orders and quotes would be ranked by time. These general requirements for ranking are applicable to all orders and quotes, unless an order or quote or modifier has a specified exception to this ranking methodology, as described in more detail below. The Exchange is proposing this ranking description instead of using the concepts of a Display Order Process and Working Order Process in Rule 6.76–O. However, substantively there would be no difference in how the Exchange would rank orders and quotes on the Pillar trading platform from how it ranks orders and quotes in the current trading system. For example, a non-displayed order would always be ranked after a displayed order at the same price, even if the non-displayed order has an earlier working time. In addition, this proposed rule is based on Rule 7.36–E(c).

Proposed Rule 6.76P–O(d) would describe how orders and quotes would be ranked based on price. Specifically, as proposed, all orders and quotes would be ranked based on the working price of an order or quote. Orders and quotes to buy would be ranked from highest working price to lowest working price and orders and quotes to sell would be ranked from lowest working price to highest working price. The rule would further provide that if the working price of an order or quote changes, the price priority of an order or quote would change. This price priority is current functionality, but the new rule would use Pillar terminology based on Rule 7.36–E(d).

Proposed Rule 6.76P–O(e) would describe the proposed priority categories for ranking purposes. As proposed, at each price, all orders and quotes would be assigned a priority category. If, at a price, there are no orders or quotes in a priority category, the next category would have first priority. The Exchange does not propose to include in Rule 6.76P–O, which sets forth the general rule regarding ranking, specifics about how one or more order or quote types may be ranked and displayed. Instead, as described in more detail below, the Exchange will address separately in new Rule 6.62P–O governing orders and modifiers which priority category correlates to different order types and modifiers. Accordingly, details regarding which proposed priority categories would be assigned to the display and reserve portions of Reserve Orders, which is currently addressed in Rule 6.76–O(a)(1)(B) and (a)(2)(A), will be addressed in proposed Rule 6.62P–O and therefore would not be included in proposed Rule 6.76P–O.

The proposed changes are also based on the priority categories for cash equity trading as set forth in Rule 7.36–E(e)(1)–(3), except for the options-specific reference to ''orders and quotes'' rather than just orders as relates to interest ranked Priority 2 and 3.

The proposed priority categories would be:

- Proposed Rule 6.76P–O(e)(1) would specify ''Priority 1—Market Orders,'' which provides that unexecuted Market Orders would have priority over all other same-side orders with the same working price. As described in greater detail below, a Market Order subject to a Trading Collar would be displayed on the Consolidated Book. In such circumstances, the displayed Market Order would have priority over all other resting orders at that price.
- Proposed Rule 6.76P–O(e)(2) would specify ''Priority 2—Display Orders.'' This proposed priority category would replace the ''Display Order Process.'' As proposed, non-marketable Limit Orders or quotes with a displayed working price would have second priority. For an order or quote that has a display price that differs from the working price of the order or quote, the order or quote would be ranked Priority 3—Non-Display Orders at the working price. This priority category is based on how Priority 2—Display Orders function on the Exchange's cash equity market, as described in Rule 7.36–E(e)(2).
- Proposed Rule 6.76P–O(e)(3) would specify ''Priority 3—Non-Display Orders.'' This priority category would be used in Pillar rules instead of reference to the ''Working Order Process.'' As proposed, non-marketable Limit Orders or quotes for which the working price is not displayed, including the reserve interest of Reserve Orders, would have third priority. This priority category is based on how Priority 3—Non-Display Orders function on the Exchange's cash equity market, as described in Rule 7.36–E(e)(3).

Proposed Rule 6.76P–O(f) would set forth that at each price level within each priority category, orders and quotes would be ranked based on time priority. The proposed changes are based on Pillar terminology in Rule 7.36–E(f)(1) and (3), except for the non-substantive reference to ''orders and quotes'' rather than just orders.

- Proposed Rule 6.76P–O(f)(1) would provide that an order or quote is assigned a working time when it is first added to the Consolidated Book based on the time such order or quote is received by the Exchange. This proposed process of assigning a working time to orders is current functionality and is substantively the same as current references to the ''time of original order entry'' found in several places in Rule 6.76–O. This proposed rule uses Pillar terminology based on Rule 7.36–E(f)(1) without any substantive differences. To provide transparency in Exchange rules, the Exchange further proposes to include in proposed Rule 6.76P–O(f) how the working time would be determined for orders that are routed. As proposed:
  - Proposed Rule 6.76P–O(f)(1)(A) would specify that an order that is fully routed to an Away Market on arrival, per proposed Rule 6.76AP–O(b)(1), would not be assigned a working time unless and until any unexecuted portion of the order returns to the Consolidated Book. The Exchange notes that this is the current process for assigning a working time to an order and uses Pillar terminology based on Rule 7.36–E(f)(1)(A) without any substantive differences.
  - Proposed Rule 6.76P–O(f)(1)(B) would specify that for an order that, on arrival, is partially routed to an Away Market, the portion that is not routed would be assigned a working time. If any unexecuted portion of the order returns to the Consolidated Book and joins any remaining resting portion of the original order, the returned portion of the order would be assigned the same working time as the resting portion of the order. If the resting portion of the original order has already executed and any unexecuted portion of the order returns to the Consolidated Book, the returned portion of the order would be assigned a new working time. This process for assigning a working time to partially routed orders is the same as currently used by the Exchange and uses Pillar terminology based on Rule 7.36–E(f)(1)(B) without any substantive differences.

• Proposed Rule 6.76P–O(f)(2) would provide that an order or quote would be assigned a new working time if: (A) The display price of an order or quote changes, even if the working price does not change, or (B) the working price of an order or quote changes, unless the working price is adjusted to be the same as the display price of an order or quote. This proposed text uses Pillar terminology based in part on Rule 7.36–E(f)(2), which provides that an order is assigned a new working time any time the working price of an order changes. The Exchange is proposing to provide greater specificity when the working time of an order would change as compared to current Rule 7.36–E(f).

• Proposed Rule 6.76P–O(f)(3) would provide that an order or quote would be assigned a new working time if the size of an order or quote increases and that an order or quote retains its working time if the size of the order or quote is decreased. This process for assigning a new working time when the size of an order changes is the same as currently used by the Exchange and uses Pillar terminology based on Rule 7.36–E(f)(3) without any substantive differences.

Proposed Rule 6.76P–O(g) would specify that the Exchange would apply ranking restrictions applicable to specified order or modifier instructions. These order and modifier instructions would be identified in proposed new Rule 6.62P–O, described below. Proposed Rule 6.76P–O(g) uses Pillar terminology based on Rule 7.36–E(g), without any substantive differences. Current Rule 6.76–O(a)(2)(C)–(E) discuss ranking of certain order types with contingencies, but the Exchange proposes that for Pillar, ranking details regarding orders with contingencies would be described in proposed Rule 6.62P–O.

Finally, proposed Rule 6.76P–O(h) would be applicable to ''Orders Executed Manually'' and would contain the same text as set forth in Rule 6.76–O(d) without any substantive differences except for the non-substantive change of capitalizing the defined term Trading Crowd (per proposed Rule 1.1), removing the superfluous clause ''in addition,'' and updating the cross-reference to reflect the new Pillar rule.[16]

In connection with proposed Rule 6.76P–O, the Exchange proposes to add the following preamble to Rule 6.76–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.76–O would not be applicable to trading on Pillar.

Proposed Rule 6.76AP–O: Order Execution and Routing

Current Rule 6.76A–O, titled ''Order Execution—OX,'' governs order execution and routing at the Exchange. The Exchange proposes that Rule 6.76AP–O would set forth the order execution and routing rules for options trading on Pillar. The Exchange proposes that the title for new Rule 6.76AP–O would be ''Order Execution and Routing'' instead of ''Order Execution—OX'' because the Exchange does not propose to use the term ''OX'' in connection with Pillar. The Exchange believes that because proposed Rule 6.76AP–O, like Rule 6.76A–O, would specify the Exchange's routing procedures, referencing to ''Routing'' in the rule's title would provide additional transparency in Exchange rules regarding what topics would be covered in new Rule 6.76AP–O. This proposed rule is based on Rule 7.37–E, which describes the order execution and routing rules for cash equity securities trading on the Pillar platform.

Proposed Rule 6.76AP–O(a) and its subparagraphs would set forth the Exchange's order execution process and would cover the same subject as the preamble to Rule 6.76A–O. However, the proposed rule would use Pillar terminology of ''Aggressing Order'' and ''Aggressing Quote''—rather than refer to an ''incoming marketable bid or offer.'' As proposed, an Aggressing Order or Aggressing Quote would be matched for execution against contra-side orders or quotes in the Consolidated Book according to the price-time priority ranking of the resting interest, subject to specified parameters.

Proposed Rule 6.76AP–O(a)(1) would set forth the LMM Guarantee, which is substantively the same as the current LMM Guarantee, as described in Rule 6.76A–O(a)(1). The Exchange proposes a substantive difference because on Pillar, the Exchange would no longer support Directed Order Market Makers or Directed Orders. Accordingly, rule text relating to Directed Order Market Makers or Directed Orders will not be included in proposed Rule 6.76AP–O.[17]

Proposed Rule 6.76AP–O(a)(1) would provide that an LMM would be entitled to an allocation guarantee when the execution price is equal to the NBB (NBO) and there is no displayed Customer interest in time priority at the NBBO in the Consolidated Book. In such cases, the Aggressing Order or Aggressing Quote would be matched against the quote of the LMM for an amount equal to 40% of the Aggressing Order or Aggressing Quote, up to the size of the LMM's quote (the ''LMM Guarantee''). With respect to how the LMM Guarantee would function on Pillar, the Exchange does not propose any substantive differences from current Rule 6.76A–O(a)(1).

Proposed Rule 6.76AP–O(a)(1)(A) proposes new functionality under Pillar and provides that if an LMM has more than one quote at a price, the LMM Guarantee would be applied among such quotes in time priority, provided there is no displayed Customer interest with time priority at each quote.

Proposed Rule 6.76AP–O(a)(1)(B), which is substantively identical to current Rule 6.76A–O(a)(1)(B), would provide that if an LMM is entitled to an LMM Guarantee (pursuant to proposed paragraph (a)(1)) and the Aggressing Order or Aggressing Quote had an original size of five (5) contracts or fewer, then such order or quote would be matched against the quote of the LMM for an amount equal to 100%, up to the size of the LMM's quote. The Exchange also proposes to add Commentary .01 to the proposed rule (which is substantively identical to Commentary .02 of current Rule 6.76A–O) to make clear that on a quarterly basis, the Exchange would evaluate what percentage of the volume executed on the Exchange comprised of orders for five (5) contracts or fewer that was allocated to LMMs and would reduce the size of the orders included in this provision if such percentage is over 40%.[18]

Proposed Rule 6.76AP–O(a)(1)(C) would specify that if the result of applying the LMM Guarantee is a fractional allocation of contracts, the LMM Guarantee would be rounded down to the nearest contract and if the result of applying the LMM Guarantee results in less than one contract, the LMM Guarantee would be equal to one contract. The Exchange believes that including this additional detail in the proposed rule would add transparency to Exchange rules.

Finally, the Exchange proposes Rule 6.76AP–O(a)(1)(D), which would provide that after applying any LMM Guarantee, the Aggressing Order or

[16] *See* proposed Rule 6.76P–O(h)(1) (removing ''in addition'') (B) (regarding ''Trading Crowd'') and (D) (updating the cross-reference to new subparagraph (B) in connection with the Section 11(a)(1)(G) of the Exchange Act and Rule 11a1–1(T) thereunder (''G exemption rule'')).

[17] The Exchange proposes to add a preamble to Rule 6.88–O (Directed Orders) to provide that the Rule would not be applicable to trading on Pillar.

[18] *See* proposed Rule 6.76AP–O, Commentary .01, which will not include cross-reference that appears in the current rule Commentary .02 to Rule 6.76A–O.

Aggressing Quote would be allocated pursuant to proposed paragraph (a) of this Rule, *i.e.,* that such orders or quotes would be matched for execution against contra-side interest resting in the Consolidated Book according to price-time priority. This proposed text is substantively identical to Rule 6.76A–O(a)(1)(C) and uses Pillar terminology.

Consistent with the Exchange's proposed approach to new Rule 6.76P–O, proposed Rule 6.76AP–O would not include references to specific order types and instead would state the Exchange's general order execution methodology. Any exceptions to such general requirements would be set forth in connection with specific order or modifier definitions in proposed Rule 6.62P–O, described below.

Proposed Rule 6.76AP–O(b) would set forth the Exchange's routing process and is intended to address the same subject as Rule 6.76A–O(c), which is currently referred to as ''Step 3'' in order processing, without any substantive differences.

Proposed Rule 6.76AP–O(b) would provide that, absent an instruction not to route, the Exchange would route marketable orders to Away Market(s) after such orders are matched for execution with any contra-side interest in the Consolidated Book in accordance with proposed paragraph (a) of this Rule regarding Order Execution. Proposed Rule 6.76AP–O(b) also uses Pillar terminology based on current Rule 7.37–E(b), which governs the Exchange's routing process on the Exchange's cash equity platform.

The proposed rule would then set forth additional details regarding routing:

- Proposed Rule 6.76AP–O(b)(1) would provide that an order that cannot meet the pricing parameters of proposed Rule 6.76AP–O(a) may be routed to Away Market(s) before being matched for execution against contra-side interest in the Consolidated Book. The Exchange believes that this proposed rule text provides transparency that an order may be routed before being matched for execution, for example, to prevent locking or crossing or trading through the NBBO. This rule uses Pillar terminology based on Rule 7.37–E(b)(1), with no substantive differences.
- Proposed Rule 6.76AP–O(b)(2) would provide that an order with an instruction not to route would be processed as provided for in proposed Rule 6.62P–O. As described in greater detail below, the Exchange proposes to describe how orders and quotes with an instruction not to route would be processed in proposed Rule 6.62P–O(e).
- Proposed Rule 6.76AP–O(b)(3) would provide that any order or portion thereof that has been routed would not be eligible to trade on the Consolidated Book, unless all or a portion of the order returns unexecuted. This routing methodology is current functionality and covers that same subject as current Rule 6.76A–O(c)(2) with no substantive differences and is based in part on Pillar terminology used in Rule 7.37–E(b)(6). In contrast to Rule 6.76A–O(c)(2), however, the Exchange proposes that Rule 6.76AP–O(b)(3) would focus on the fact that once routed, an order would not be eligible to trade on the Consolidated Book, rather than stating the obvious that it would be subject to the routing destination's trading rules once routed. In addition, because, as discussed above, the working time assigned to orders that are routed is being proposed to be addressed in new Rule 6.76P–O(f)(1)(A) and (B), the Exchange believes it would be unnecessary to restate this information in new Rule 6.76AP–O.
- Proposed Rule 6.76AP–O(b)(4) would provide that requests to cancel an order that has been routed in whole or part would not be processed unless and until all or a portion of the order returns unexecuted. This proposed rule is based on Pillar terminology used in Rule 7.37–E(b)(7)(A) without any substantive differences.
- Finally, proposed Rule 6.76AP–O(c) would provide that after trading with eligible contra-side interest on the Consolidated Book and/or returning unexecuted after routing to Away Market(s), any unexecuted non-marketable portion of an order would be ranked consistent with new Rule 6.76P–O. This rule represents current functionality and is based on Rule 6.76A–O generally and paragraph (c)(2)(C) as it pertains to orders that were routed away without any substantive differences. This proposed rule is also based on Pillar terminology used in Rule 7.37–E(c) without any substantive differences.

The Exchange believes that the specific routing methodologies for an order type or modifier should be included with how the order type is defined, which will be in proposed Rule 6.62P–O. Accordingly, the Exchange does not believe it needs to specify in proposed Rule 6.76AP–O whether an order is eligible to route, and if so, whether there are any specific routing instructions applicable to the order and therefore will not be carrying over such specifics that are currently included in Rule 6.76A–O.

In connection with proposed Rule 6.76AP–O, the Exchange proposes to add the following preamble to Rule 6.76A–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.76A–O would not be applicable to trading on Pillar.

Proposed Rule 6.62P–O: Orders and Modifiers

Current Rule 6.62–O (Certain Types of Orders Defined) defines the order types that are currently available for options trading both on the OX system and for open outcry trading on the Exchange. The Exchange proposes that new Rule 6.62P–O would set forth the order types and modifiers that would be available for options trading both on Pillar (*i.e.,* electronic order entry) and in open outcry trading. The Exchange proposes to specify that Rule 6.62–O would not be applicable to trading on Pillar.

Because certain order types and modifiers that would be available for options trading on Pillar are based on, or similar to, order types and modifiers available on the Exchange's cash equity market, the Exchange proposes to structure proposed Rule 6.62P–O based on Rule 7.31–E and use similar terminology. The Exchange also proposes to title proposed Rule 6.62P–O as ''Orders and Modifiers,'' which is the title of Rule 7.31–E.

Primary Order Types. Proposed Rule 6.62P–O(a) would specify the Exchange's primary order types, which would be Market Orders and Limit Orders, and is based on Rule 7.31–E(a), which sets forth the Exchange's cash equity primary order types. Similar to Rule 7.31–E(a), proposed Rule 6.62P–O(a) would also set forth the Exchange's proposed Limit Order Price Protection functionality and Trading Collars.

Market Orders. Proposed Rule 6.62P–O(a)(1) would define a Market Order as an unpriced order message to buy or sell a stated number of option contracts at the best price obtainable, subject to the Trading Collar assigned to the order, and would further specify that unexecuted Market Orders may be designated Day or GTC, which represents current functionality,[19] and

[19] The ability for a Market Order to be designated Day or GTC is based on current Rules 6.62–O(m) (describing a ''Day Order'') and 6.62–O(n) (describing a ''Good-til-Cancelled Order'' or ''GTC Order'') and Commentary .01 to Rule 6.62–O, which requires all orders to be either ''day,'' ''immediate or cancel,'' or ''good 'til cancelled.'' As described in more detail below, on Pillar, the time-in-force designation, *e.g.,* Day or GTC, would be a modifier that can be added to an order type and will not be described in the rules as a separate order type. Similar to Rule 7.31–E, the Exchange will specify which time-in-force designations are available for each order type.

that unexecuted Market Orders would be ranked Priority 1—Market Orders. This proposed rule text uses Pillar terminology similar to Rule 7.31–E(a)(1), but with differences to reflect options trading.

Proposed Rule 6.62P–O(a)(1) would further provide that for purposes of processing Market Orders, the Exchange would not use an adjusted NBBO.[20] On the Exchange's cash equity market, the Exchange does not use an adjusted NBBO when processing Market Orders. The Exchange proposes to similarly not use an adjusted NBBO when processing Market Orders on its options market.

Proposed Rule 6.62P–O(a)(1)(A) would provide that a Market Order that arrives during continuous trading would be rejected, or that was routed, returns unexecuted, and has no resting quantity to join would be cancelled if it fails the validations specified in proposed Rule 6.62P–O(a)(1)(A)(i)—(iv). This proposed rule is based in part on Rule 6.62–O(a), which specifies circumstances when a Market Order will be rejected during Core Trading Hours, with differences to use Pillar terminology and to modify the circumstances when a Market Order would be rejected. As proposed, a Market Order would be rejected (or cancelled if routed first) if:[21]

- There is no NBO (proposed Rule 6.62P–O(a)(1)(A)(i)).
- There is no NBB and the NBO is higher than $0.50 (for sell Market Orders only). The Exchange further proposes that if there is no NBB and the NBO is $0.50 or below, a Market Order to sell would not be rejected and would have a working price and display price one MPV above zero and would not be subject to a Trading Collar (proposed Rule 6.62P–O(a)(1)(A)(ii)). The proposed rule would further provide that a Market Order to sell would be cancelled if it was assigned a Trading Collar, routed, and when it returns unexecuted, it has no resting portion to join and there is no NBB, regardless of the price of the NBO. Accordingly, in this scenario, if there were no NBB and an NBO that is $0.50 or below, the returned, unexecuted Market Order would be cancelled rather than displayed at one MPV above zero.
- There are no contra-side Market Maker quotes on the Exchange or contra-side Away Market NBBO, provided that a Market Order to sell would be accepted as provided for in proposed Rule 6.62P–O(a)(1)(A)(ii) (proposed Rule 6.62P–O(a)(1)(A)(iii)).
- The NBBO is not locked or crossed and the spread is equal to or greater than a minimum amount based on the midpoint of the NBBO (proposed Rule 6.62P–O(a)(1)(A)(iv)). The proposed ''wide-spread'' parameter is based in part on Rule 6.87–O(b)(3) with two differences. First, the first bucket would include $2.00, instead of capping at $1.99, and second, the wide-spread calculation would be based off of the midpoint of the NBBO, rather than off of the bid price, as follows:

The midpoint of the NBBO	Spread parameter
$0.00 to $2.00	$0.75
Above $2.00 to and including $5.00	1.25
Above $5.00 to and including $10.00	1.50
Above $10.00 to and including $20.00	2.50
Above $20.00 to and including $50.00	3.00
Above $50.00 to and including $100.00	4.50
Above $100.00	6.00

Proposed Rule 6.62P–O(a)(1)(B) would provide that an Aggressing Market Order to buy (sell) would trade with all orders or quotes to sell (buy) on the Consolidated Book priced at or below (above) the Trading Collar before routing to Away Market(s) at each price. Proposed Rule 6.62P–O(a)(1)(B) would further provide that after trading or routing, or both, a Market Order would be displayed at the Trading Collar, subject to proposed Rule 6.62P–O(a)(1)(C), which is consistent with current functionality that Market Orders would be displayed at a trading collar, per Rule 6.60–O(a)(5).

Proposed Rule 6.62P–O(a)(1)(C) would provide that a Market Order would be cancelled before being displayed if there are no remaining contra-side Market Maker quotes on the Exchange or contra-side Away Market NBBO. Proposed Rule 6.62P–O(a)(1)(D) would provide that a Market Order would be cancelled after being displayed at its Trading Collar if there ceases to be a contra-side NBBO. These proposed cancellation events are based on a subset of the scenarios of when a Market Order would have been rejected on arrival, and the Exchange believes it is appropriate to cancel a Market Order either before it is displayed, or after it is displayed, in these circumstances in order to prevent the potential for such order to be displayed when there is no real market in a series.

Finally, proposed Rule 6.62P–O(a)(1)(E) would provide that a resting, displayed Market Order that is locked or crossed by an Away Market would be routed to that Away Market. Because Market Orders are intended to obtain the best price obtainable, the Exchange proposes to route displayed Market Orders if they are locked or crossed by an Away Market.[22]

Limit Orders. Proposed Rule 6.62P–O(a)(2) would define a Limit Order as an order message to buy or sell a stated number of option contracts at a specified price or better, subject to Limit Order Price Protection and the Trading Collar assigned to the order, and that a Limit Order may be designated Day, IOC, or GTC. In addition, unless otherwise specified, the working price and the display price of a Limit Order would be equal to the limit price of the order, it is eligible to be routed, and it would be ranked Priority 2—Display Orders. This proposed rule text uses Pillar terminology that is based in part on Rule 7.31–E(a)(2). The ability for a Limit Order to be designated Day, IOC, or GTC is based on current Rules 6.62–O(m) and 6.62–O(n). In addition, marketable limit orders are currently subject to trading collars.

Proposed Rule 6.62P–O(a)(2)(A) would provide that a marketable Limit Order to buy (sell) received by the Exchange would trade with all orders and quotes to sell (buy) on the Consolidated Book priced at or below (above) the NBO (NBB) before routing to an Away Market NBO (NBB) and may route to prices higher (lower) than the NBO (NBB) only after trading with orders and quotes to sell (buy) on the Consolidated Book at each price point, and once no longer marketable, the Limit Order would be ranked and displayed on the Consolidated Book. This proposed rule text is based on Rule 7.31–E(a)(2)(A), with non-substantive differences to use terminology specific to options trading.

Limit Order Price Protection. The Exchange proposes to describe its

[20] *See* discussion *supra,* regarding the proposed Rule 1.1 definition of ''NBBO.''

[21] The Exchange will also reject a Market Order if it is entered when the underlying NMS stock is either in a Limit State or a Straddle State, which is current functionality. *See* Rule 6.65A–O(a)(1). The Exchange proposes a non-substantive amendment to Rule 6.65A–O(a)(1) to add a cross reference to proposed Rule 6.62P–O(a)(1). The Exchange also proposes to amend the second sentence of Rule 6.65A–O(a)(1) to remove references to trading collars, and instead specify that the Exchange would cancel any resting Market Orders if the underlying NMS stock enters a Limit State or a Straddle State and would notify OTP Holders of the reason for such cancellation. This proposed change would describe both how Market Orders function today on the OX system and how they would be processed on Pillar.

[22] As described above for proposed Rule 6.76P–O(b)(3), displayed interest other than displayed Market Orders would stand their ground if locked or crossed by an Away Market. The Exchange would provide an option for Limit Orders to instead be routed, *see* discussion *infra,* regarding proposed Rule 6.62P–O(i)(1) and the proposed Proactive if Locked/Crossed Modifier.

proposed Limit Order Price Protection functionality in proposed Rule 6.62P–O(a)(3). On the OX system, the concept of ''Limit Order Price Protection'' for orders is set forth in Rule 6.60–O(b) and is called the ''Limit Order Filter.'' For quotes, price protection filters are described in Rule 6.61–O. The proposed ''Limit Order Price Protection'' on Pillar would be applicable to both Limit Orders and quotes and would work similarly to how the current price protection mechanisms function on the OX system in that a Limit Order or quote would be rejected if it is priced a specified percentage away from the contra-side NBB or NBO. However, on Pillar, the Exchange proposes to use new thresholds and reference prices that would be applicable to both orders and quotes.

Proposed Rule 6.62P–O(a)(3)(A) would provide that each trading day, a Limit Order or quote to buy (sell) would be rejected or cancelled (if resting) if it is priced at a ''Specified Threshold,'' described below, above (below) the Reference Price, rounded down to the nearest price within the MPV for the Series (''Limit Order Price Protection''). In other words, a Limit Order designated GTC would be re-evaluated for Limit Order Price Protection on each day that it is eligible to trade and would be cancelled if the limit price is through the Specified Threshold. In addition, the rounding feature is based on how Limit Order Price Protection is calculated on the Exchange's cash equity market if it is not within the MPV for the security, as described in the last sentence of Rule 7.31–E(a)(2)(B). The proposed rule would further provide that Cross Orders and Limit-on-Open (''LOO'') Orders (described below) would not be subject to Limit Order Price Protection and that Limit Order Price Protection would not be applied to a Limit Order or quote if there is no Reference Price.

- Proposed Rule 6.62P–O(a)(3)(A)(i) would provide that a Limit Order or quote that arrives when a series is open would be evaluated for Limit Order Price Protection on arrival.
- Proposed Rule 6.62P–O(a)(3)(A)(ii) would provide that a Limit Order or quote received during a pre-open state would be evaluated for Limit Order Price Protection after an Auction concludes.[23]
- Proposed Rule 6.62P–O(a)(3)(A)(iii) would provide that a Limit Order or quote that was resting on the Consolidated Book before a trading halt would be evaluated for Limit Order Price Protection again after the Trading Halt Auction concludes.

Proposed Rule 6.62P–O(a)(3)(B) would specify that the Reference Price for calculating Limit Order Price Protection for an order or quote to buy (sell) would be the NBO (NBB), provided that, immediately following an Auction, the Reference Price would be the Auction Price, or if none, the upper (lower) Auction Collar price, or, if none, the NBO (NBB). The Exchange believes that adjusting the Reference Price for Limit Order Price Protection immediately following an Auction would ensure that the most up-to-date price would be used to assess whether to cancel a Limit Order that was received during a pre-open state or would be reevaluated after a Trading Halt Auction. The Exchange further proposes that for purposes of calculating Limit Order Price Protection, the Exchange would not use an adjusted NBBO, which is based on how Limit Order Price Protection currently functions on the Exchange's cash equity market, as described in Rule 7.31–E(a)(2)(B).[24]

Proposed Rule 6.62P–O(a)(3)(C) would specify the Specified Threshold and would provide that unless determined otherwise by the Exchange and announced to OTP Holders and OTP Firms by Trader Update, the Specified Threshold applicable to Limit Order Price Protection would be:

Reference price	Specified threshold
$0.00 to $1.00	$0.30
$1.01 to $10.00	50%
$10.01 to $20.00	40%
$20.01 to $50.00	30%
$50.01 to $100.00	20%
$100.01 and higher	10%

The Exchange believes that the proposed thresholds are more granular than those currently specified in Rules 6.60–O(b) (for orders) and 6.61–O(a)(1)(A) and (B) (for quotes) and therefore determining whether to reject a Limit Order or quote will be more tailored to the applicable Reference Price. In addition, consistent with Rules 6.60–O(b) and 6.61–O(a)(1), the Exchange proposes that these thresholds could change, subject to announcing the changes by Trader Update. Providing flexibility in Exchange rules regarding how the Specified Thresholds would be set is consistent with the rules of other options exchanges.[25]

Trading Collar. Trading Collars on the OX system are currently described in Rule 6.60–O(a). Under the current rules, incoming Market Orders and marketable Limit Orders are limited in having an immediate execution if they would trade at a price greater than one ''Trading Collar.'' A collared order is displayed at that price and then can be repriced to new collars as the NBBO updates. On Pillar, the Exchange proposes new Trading Collar functionality.

Unlike current functionality, which permits a collared order to be repriced, as proposed, a Market Order or Limit Order would be assigned a single Trading Collar that would be applicable to that order until it is fully executed or cancelled. The new proposed Trading Collar would function as a ceiling (for buy orders) or floor (for sell orders) of the price at which such order could be traded, displayed, or routed. The Exchange further proposes that when an order is working at its assigned Trading Collar, it would cancel if not executed within a specified time period.

Proposed Rule 6.62P–O(a)(4) would provide that a Market Order or Limit Order to buy (sell) would not trade or route to an Away Market at a price above (below) the Trading Collar assigned to that order. As further proposed, Auction-Only Orders, Limit Orders designated IOC or FOK, Cross Orders, ISOs, and Market Maker quotes would not be subject to Trading Collars, which is consistent with current functionality.[26] In addition, Trading Collars would not be applicable during Auctions.

Proposed Rule 6.62P–O(a)(4)(A) would provide that a Trading Collar assigned to an order would be calculated once per trading day and would not be updated. Accordingly, an order designated GTC would receive a new Trading Collar each day, but that Trading Collar would not be updated intraday. The rule would further provide that a Market Order or Limit Order that is received during continuous trading would be assigned a Trading Collar before being processed for either trading, repricing, or routing

[23] *See* discussion *infra,* regarding proposed Rule 6.64P–O(a) and proposed definitions for the terms ''Auction,'' ''Auction Price,'' ''Auction Collar,'' ''pre-open state,'' and ''Trading Halt Auction.''

[24] References to the NBBO, NBB, and NBO in Rule 7.31–E refer to using a determination of the national best bid and offer that has not been adjusted.

[25] *See, e.g.,* CBOE Exchange, Inc. (''Cboe'') Rule 5.34(a)(4) (describing the ''Drill-Through Protection'' and that Cboe ''determines the buffer amount on a class and premium basis''); and the Nasdaq Stock Market LLC (''Nasdaq'') Options 3, Section 15(a)(1)(B) (specifying that ''Order Price Protection'' can be a configurable dollar amount specified by Nasdaq and announced via an Options Trader Alert).

[26] *See* Rule 6.60–O(a)(3) (''Trade Collar Protection does not apply to quotes, IOC Orders, AON Orders, FOK Orders, and NOW Orders.'').

and that an order that is routed on arrival and returned unexecuted would use the Trading Collar assigned upon arrival. In addition, a Market Order or Limit Order received during a pre-open state would be assigned a Trading Collar after an Auction concludes.

Proposed Rule 6.62P–O(a)(4)(B) would provide that the Reference Price for calculating the Trading Collar for an order to buy (sell) would be the NBO (NBB). The proposed rule would further provide that for Auction-eligible orders to buy (sell) that were received during a pre-open state and are assigned a Trading Collar after the Auction concludes, the Reference Price would be the Auction Price or, if none, the upper (lower) Auction Collar price or, if none, the NBO (NBB). For purposes of calculating a Trading Collar, the Exchange would not use an adjusted NBBO. Proposed Rule 6.62P–O(a)(4)(B)(i) would further provide that a Trading Collar would not be assigned to a Limit Order if there is no Reference Price at the time of calculation. And proposed Rule 6.62P–O(a)(4)(B)(ii) would provide that after an Auction, if a Market Order has not already been assigned a Trading Collar and there is no Reference Price, the order would be cancelled.

Proposed Rule 6.62P–O(a)(4)(C) would describe how the Trading Collar would be calculated and would provide that the Trading Collar for an order to buy (sell) would be a specified amount above (below) the Reference Price, as follows: (1) For orders with a Reference Price of $1.00 or lower, $0.25; or (2) for orders with a Reference Price above $1.00, the lower of $2.50 or 25%. Proposed Rule 6.62P–O(a)(4)(C)(i) would further provide that if the calculation of a Trading Collar would not be in the MPV for the series, it would be rounded down to the nearest price within the applicable MPV (this proposed functionality is based on how Trading Collars are calculated on the Exchange's cash equity market, as described in Rule 7.31–E(a)(1)(B)). Proposed Rule 6.62P–O(a)(4)(C)(ii) would further provide that for orders to sell, if subtracting the Trading Collar from the Reference Price would result in a negative number, the Trading Collar for Limit Orders would be the limit price and the Trading Collar for Market Orders would be one MPV above zero.

Proposed Rule 6.62P–O(a)(4)(D) would describe how the Trading Collar would be applied and would provide that if an order to buy (sell) would trade or route above (below) the Trading Collar or would have its working price repriced to a Trading Collar that is below (above) its limit price, the order would be added to the Consolidated Book at the Trading Collar for 500 milliseconds and if not traded within that period, would be cancelled. In addition, once the 500-millisecond timer begins for an order, the order would be cancelled at the end of the timer even if it repriced or has been routed to an Away Market during that period, in which case any portion of the order that is returned unexecuted would be cancelled.

The Exchange believes that the proposed Trading Collar functionality is designed to provide a similar type of order protection as is currently available (as described in Rule 6.60–O(a)) because it would limit the price at which a marketable order could be traded, routed, or displayed. The Exchange believes that the proposed differences are designed to simplify the functionality by applying a static ceiling price (for buy orders) or floor price (for sell orders) at which such order could be traded or routed that would be determined at the time of entry, and would be applicable to the order until it is traded or cancelled. The Exchange believes that the proposed functionality would provide greater determinism to an OTP Holder or OTP Firm of the Trading Collar that would be applicable to a Market Order or Limit Order and when such order may be cancelled if it reaches its Trading Collar.

Time in Force Modifiers. Proposed Rule 6.62P–O(b) would set forth the time-in-force modifiers that would be available for options trading on Pillar and is based on Rule 7.31–E(b). The Exchange proposes to offer the same time-in-force modifiers that are currently available for options trading on the Exchange and use Pillar terminology to describe the functionality. As noted above, the Exchange proposes to describe the Time in Force Modifiers in proposed Rule 6.62P–O(b), and then specify for each order type which Time in Force Modifiers would be available for such orders or quotes.

Day Modifier. Proposed Rule 6.62P–O(b)(1) would provide that any order or quote to buy or sell designated Day, if not traded, would expire at the end of the trading day on which it was entered and that a Day Modifier cannot be combined with any other Time in Force Modifier. This proposed rule text is based on Rule 7.31–E(b)(1) with one difference to reference ''quotes'' in addition to orders. This proposed functionality would operate no differently than how a ''Day Order,'' as described in Rule 6.62–O(m), currently functions.

Immediate-or-Cancel (''IOC'') Modifier. Proposed Rule 6.62P–O(b)(2) would provide that a Limit Order may be designated IOC or Routable IOC, as described in proposed Rules 6.62P–O(b)(2)(A) and (B) and that a Limit Order designated IOC would not be eligible to participate in any Auctions. This proposed rule text is based on the first and third sentences of Rule 7.31–E(b)(2) without any differences and is also based on current functionality. The Exchange proposes to use Pillar terminology based on Rule 7.31–E(b)(2) to describe this functionality.

Proposed Rule 6.62P–O(b)(2)(A) would define a ''Limit IOC Order'' as a Limit Order designated IOC that would be traded in whole or in part on the Exchange as soon as such order is received, and the unexecuted quantity would be cancelled and that a Limit IOC Order does not route. This proposed rule text is based on Rule 7.31–E(b)(2)(A) without any substantive differences. The proposed Pillar Limit IOC Order would function the same as an ''Immediate-or-Cancel Order (IOC Order),'' as currently described in Rule 6.62–O(k), without any differences.

Proposed Rule 6.62P–O(b)(2)(B) would define a ''Limit Routable IOC Order'' as a Limit Order designated Routable IOC that would be traded in whole or in part on the Exchange as soon as such order is received, and the unexecuted quantity routed to Away Market(s) and that any quantity not immediately traded either on the Exchange or an Away Market would be cancelled. This proposed rule text is based on Rule 7.31–E(b)(2)(B) without any substantive differences. The proposed Pillar Limit Routable IOC Order is also based on the ''NOW Order,'' as currently described in Rule 6.62–O(o) and uses Pillar terminology.

Fill-or-Kill (''FOK'') Modifier. Proposed Rule 6.62P–O(b)(3) would provide that a Limit Order designated FOK would be traded in whole on the Exchange as soon as such order is received, and if not so traded is to be cancelled and that a Limit Order designated FOK does not route and does not participate in any Auctions. The Exchange does not offer the FOK Modifier on its cash equity market, and this proposed rule uses Pillar terminology to offer the same functionality that is currently described in Rule 6.62–O(l) as the ''Fill-or-Kill Order (FOK Order)'' without any substantive differences.

Good-'Til-Cancelled (''GTC'') Modifier. Proposed Rule 6.62P–O(b)(4) would provide that a Limit or Market Order designated GTC remains in force until the order is filled, cancelled, the

MPV in the series changes overnight, the option contract expires, or a corporate action results in an adjustment to the terms of the option contract. The Exchange does not offer the GTC Modifier on its cash equity market, and this proposed rule uses Pillar terminology to offer the same functionality that is currently described in Rule 6.62–O(n) as the ''Good-Till-Cancelled (GTC Order)'' without any substantive differences.

Auction-Only Orders. Proposed Rule 6.62P–O(c) would define an ''Auction-Only Order'' as a Limit Order or Market Order that is to be traded only in an Auction pursuant to Rule 6.64P–O,[27] which is text based on Rule 7.31–E(c). The proposed rule would further provide that an Auction-Only Order would not be accepted when a series is opened for trading and any portion of an Auction-Only Order that is not traded in a Core Open Auction or Trading Halt Auction would be cancelled. This represents current functionality and is based in part on the last sentence of Rule 7.31–E(c)(1), the last sentence of Rule 7.31–E(c)(2), and the last sentence of Rule 6.62–O(r), which defines an ''Opening Only Order.''

Proposed Rule 6.62P–O(c)(1) would define a ''Limit-on-Open Order ('LOO Order')'' as a Limit Order that is to be traded only in an Auction. This proposed rule uses Pillar terminology based on Rule 7.31–E(c)(1) to describe functionality that would be no different from current functionality, as described in Rule 6.62–O(r).

Proposed Rule 6.62P–O(c)(2) would define a ''Market-on-Open Order ('MOO Order')'' as a Market Order that is to be traded only in an Auction. This proposed rule uses Pillar terminology based on Rule 7.31–E(c)(2) to describe functionality that would be no different from current functionality, as described in Rule 6.62–O(r).

Proposed Rule 6.62P–O(c)(3) would define an ''Imbalance Offset Order ('IO Order').'' The Exchange currently offers an IO Order for participation in Trading Halt Auctions on its cash equity market but does not offer this order type for options trading on the OX system. For cash equity trading, the IO Order is a conditional order type that is eligible to participate in a Trading Halt Auction only if it would offset the imbalance. For options trading on Pillar, the Exchange proposes to offer the IO Order for both Core Open Auctions and Trading Halt Auctions.

As proposed, the IO Order would function no differently than how an IO Order currently functions on the Exchange's cash equity market. Accordingly, proposed Rule 6.62P–O(c)(3) would define an IO Order as a Limit Order that is to be traded only in an Auction, which is based in part on Rule 7.31–E(c)(5).

- Proposed Rule 6.62P–O(c)(3)(A) would provide that an IO Order would participate in an Auction only if: (1) There is an Imbalance in the series on the opposite side of the market from the IO Order after taking into account all other orders and quotes eligible to trade at the Indicative Match Price; and (2) the limit price of the IO Order to buy (sell) would be at or above (below) the Indicative Match Price. This proposed text is based on Rule 7.31–E(c)(5)(B) without any substantive differences.
- Proposed Rule 6.62P–O(c)(3)(B) would provide that the working price of an IO Order to buy (sell) would be adjusted to be equal to the Indicative Match Price, provided that the working price of an IO Order would not be higher (lower) than its limit price. This proposed text is based on Rule 7.31–E(c)(5)(C) without any differences.

Orders with a Conditional or Undisplayed Price and/or Size. Proposed Rule 6.62P–O(d) would set forth the orders with a conditional or undisplayed price and/or size that would be available for options trading on Pillar. On Pillar, the Exchange proposes to offer the same type of orders that are available in the OX system and that are currently described in Rule 6.62–O(d) as a ''Contingency Order or Working Order,'' with changes as described below.

Reserve Order. Reserve Orders are currently defined in Rule 6.62–O(d)(3). The Exchange proposes that for options traded on Pillar, Reserve Orders would function similarly to how Reserve Orders function on its cash equity market, as described in Rule 7.31–E(d)(1). Accordingly, the Exchange proposes that proposed Rule 6.62P–O(d)(1), which would define Reserve Orders for options trading on Pillar, would be based on Rule 7.31–E(d)(1), with differences only to reflect differences in options and cash equity trading. For example, options trading does not have a concept of ''round lot'' or ''odd lot'' trading, and therefore the proposed options trading version of the Rule would not include description of behavior that correlates to such functionality.

Proposed Rule 6.62P–O(d)(1) would define a Reserve Order as a Limit Order with a quantity of the size displayed and with a reserve quantity of the size (''reserve interest'') that is not displayed and that the displayed quantity of a Reserve Order is ranked Priority 2—Display Orders and the reserve interest is ranked Priority 3—Non-Display Orders. This proposed rule text is based on Rule 7.31–E(d)(1) without any differences. Proposed Rule 6.62P–O(d)(1) would further provide that both the display quantity and the reserve interest of an arriving marketable Reserve Order would be eligible to trade with resting interest in the Consolidated Book or route to Away Markets, unless designated as a Non-Routable Limit Order, which is based on the third sentence of Rule 7.31–E(d)(1) with a non-substantive difference to add reference to Non-Routable Limit Order.

Proposed Rule 6.62P–O(d)(1) would further provide that the working price of the reserve interest of a resting Reserve Order to buy (sell) would be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule, provided that it would never be priced higher (lower) than the working price of the display quantity of the Reserve Order. This proposed rule text is based on the last sentence of Rule 7.31–E(d)(1) with one difference to reference that the reserve interest could never have a working price that is more aggressive than the working price of the display quantity of the Reserve Order, which would be new functionality on Pillar designed to ensure that the reserve interest of a Reserve Order to buy (sell) would never trade at a price higher (lower) than the working price of the display quantity of the Reserve Order.[28]

- Proposed Rule 6.62P–O(d)(1)(A) would provide that the displayed portion of a Reserve Order would be replenished when the display quantity is decremented to zero and that the replenish quantity would be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity. This proposed rule text is based on Rule 7.31–E(d)(1)(A) with differences to reflect that options are not traded in ''round lots'' or ''odd lots.'' Accordingly, the Exchange would not replenish a Reserve Order on the options trading platform until the display portion is fully decremented.
- Proposed Rule 6.62P–O(d)(1)(B) would provide that each time the

[27] *See* discussion *infra,* regarding proposed Rule 6.64P and definitions relating to Auctions.

[28] For example, as described in more detail below, the proposed Non-Routable Limit Order would be eligible to be repriced only once after it is resting in the Consolidated Book (see proposed Rule 6.62P–O(e)(1)). If the display quantity of a Non-Routable Limit Order that is combined with a Reserve Orders has already been repriced and is no longer eligible to be repriced, and the Away Market NBBO adjusts, the reserve quantity would not adjust to a price that would be more aggressive than the working price of the display quantity of the order.

display quantity of a Reserve Order is replenished from reserve interest, a new working time would be assigned to the replenished quantity. This proposed rule text is based in part on Rule 7.31–E(d)(1)(B) with differences to reflect that for options traded on Pillar, there would never be more than one display quantity of a Reserve Order, and therefore the Exchange would not have different ''child'' display quantities of a Reserve Order with different working times, as could occur for a Reserve Order on the Exchange's cash equity trading platform.

• Proposed Rule 6.62P–O(d)(1)(C) would provide that a Reserve Order may be designated as a Non-Routable Limit Order and if so designated, the reserve interest that replenishes the display quantity would be assigned a display price and working price consistent with the instructions for the order. This proposed rule text is based on Rule 7.31–E(d)(1)(B)(ii) without any substantive differences.

• Proposed Rule 6.62P–O(d)(1)(D) would provide that a routable Reserve Order would be evaluated for routing both on arrival and each time the display quantity is replenished. Proposed Rule 6.62P–O(d)(1)(D)(i) would provide that if routing is required, the Exchange would route from reserve interest before publishing the display quantity. And proposed Rule 6.62P–O(d)(1)(D)(ii) would provide that any quantity of a Reserve Order that is returned unexecuted would join the working time of the reserve interest and that if there is no reserve interest to join, the returned quantity would be assigned a new working time. This proposed rule text is based on Rule 7.31–E(d)(1)(D) and subparagraphs (i) and (ii) with differences to reflect that there is no concept of round lots or multiple child display orders for options trading.

• Proposed Rule 6.62P–O(d)(1)(E) would provide that a request to reduce the size of a Reserve Order would cancel the reserve interest before cancelling the display quantity. This proposed rule text is based on Rule 7.31–E(d)(1)(E) with differences only to reflect that there would not be more than one child display order for options trading of Reserve Orders on Pillar.

• Proposed Rule 6.62P–O(d)(1)(F) would provide that a Reserve Order may be designated Day or GTC, but it may not be designated as an ALO Order. This proposed rule text is based in part on Rule 7.31–E(d)(1)(C), with differences to reflect that the GTC Modifier would be available for Reserve Orders trading on the Pillar options trading platform and that Primary Pegged Orders would not be available for options traded on Pillar.

Non-Displayed Limit Order. The Exchange proposes to offer the Non-Displayed Limit Order for options trading on Pillar, which would be new for options trading and is based on the existing Non-Displayed Limit Order as described in Rule 7.31–E(d)(2).[29] Proposed Rule 6.62P–O(d)(2) would define a Non-Displayed Limit Order as a Limit Order that is not displayed, does not route, and is ranked Priority 3—Non-Display Orders; and that a Non-Displayed Limit Order may be designated Day or GTC and would not participate in any Auctions. This proposed rule text is based on Rule 7.31–E(d)(2) with differences to reflect that the GTC Time-in-Force Modifier is available for options trading on Pillar.

• Proposed Rule 6.62P–O(d)(2)(A) would provide that the working price of a Non-Displayed Limit Order would be assigned on arrival and adjusted when resting on the Consolidated Book and that the working price of a Non-Displayed Limit Order to buy (sell) would be the lower (higher) of the limit price or the NBO (NBB). This proposed rule text is based on Rule 7.31–E(d)(2)(A) with non-substantive differences to reference the Consolidated Book instead of the NYSE Arca Book and to streamline the rule text without any substantive differences.

• Proposed Rule 6.62P–O(d)(2)(B) would provide that a Non-Displayed Limit Order may be designated with a Non-Display Remove Modifier and if so designated, a resting Non-Displayed Limit Order to buy (sell) with a working price equal to the working price of an ALO Order or Day ISO ALO to sell (buy) would trade as the liquidity taker against such order. This functionality would be new for options trading and is based on the Non-Display Remove Modifier functionality available on the cash equity market as described in Rule 7.31–E(d)(2)(B), without any substantive differences.

All-or-None (''AON'') Order. AON Orders are currently defined in Rule 6.62–O(d)(4). AON Orders are not available on the Exchange's cash equity market, and for options trading on Pillar, would function similarly to how AON Orders currently function because such orders would only execute if they can be satisfied in their entirety. However, unlike the OX system, where AON Orders are not integrated in the Consolidated Book, on Pillar, the Exchange proposes that AON Orders would be ranked in the Consolidated Book and function as conditional orders that would trade only if their condition could be met, similar to how orders with a Minimum Trade Size (''MTS'') Modifier function on Pillar on the Exchange's cash equity market. Because of the new functionality that would be available for AON Orders on Pillar, the Exchange proposes to use Pillar terminology to describe this order type.

Proposed Rule 6.62P–O(d)(3) would provide that an AON Order is a Limit Order that is to be traded in whole on the Exchange at the same time or not at all, which represents current functionality as described in the first sentence of Rule 6.62–O(d)(4). Proposed Rule 6.62P–O(d)(3) would further provide that an AON Order that does not trade on arrival would be ranked Priority 3—Non-Display Orders and that an AON Order may be designated Day or GTC, does not route, and would not participate in any Auctions. This proposed rule text uses Pillar terminology to describe the proposed new functionality that such orders would be ranked on the Consolidated Book.

• Proposed Rule 6.62P–O(d)(3)(A) would provide that the working price of an AON Order would be assigned on arrival and adjusted when resting on the Consolidated Book and that the working price of an AON Order to buy (sell) would be the lower (higher) of the limit price or NBO (NBB). Because an AON Order is non-displayed, the Exchange proposes that its working price should be adjusted in the same manner as the proposed Non-Displayed Limit Order.

• Proposed Rule 6.62P–O(d)(3)(B) would provide that an Aggressing AON Order to buy (sell) would trade with sell (buy) orders and quotes that in the aggregate can satisfy the AON Order in its entirety. This proposed rule text is new and promotes clarity in Exchange rules that an Aggressing AON Order (whether on arrival or as a resting order that becomes an Aggressing Order) would be eligible to trade with more than one contra-side order or quote, provided that multiple orders and quotes in the aggregate would satisfy the AON Order in its entirety.

• Proposed Rule 6.62P–O(d)(3)(C) would provide that a resting AON Order to buy (sell) would trade with an Aggressing Order or Aggressing Quote to sell (buy) that individually can satisfy the whole AON Order. This is proposed new functionality, because currently, an AON Order can trade only against resting interest in the Consolidated Book. The Exchange believes this

[29] The Exchange notes that a Non-Displayed Limit Order would function similarly to a PNP Blind Order that locks or crosses the contra-side NBBO. In such case, a PNP Blind Order would not be displayed, as described in Rule 6.62–O(u) (''if the PNP Blind Order would lock or cross the NBBO, the price and size of the order will not be disseminated'').

proposed change would provide an AON Order with additional execution opportunities.

• Proposed Rule 6.62P–O(d)(3)(C)(i) would provide that if an Aggressing Order or Aggressing Quote to sell (buy) does not satisfy the resting AON Order to buy (sell), that Aggressing Order or Aggressing Quote would not trade with and may trade through such AON Order. Proposed Rule 6.62P–O(d)(3)(C)(ii) would further provide that if a resting non-displayed order to sell (buy) does not satisfy the quantity of a same-priced resting AON Order to buy (sell), a subsequently arriving order or quote to sell (buy) that satisfies the AON Order would trade before such resting non-displayed order or quote to sell (buy) at that price. Both of these proposed rules are consistent with current Rule 6.62–O(d)(4), which provides that an AON Order does not have ''standing in any Order Process in the Consolidated Book,'' *i.e.,* a resting AON Order can be ignored if its condition is not met. This proposed rule text is also based on how the MTS Modifier functions on the cash equity market, as described in Rule 7.31–E(i)(3)(E)(i) and (ii).

• Proposed Rule 6.62P–O(d)(3)(D) would provide that a resting AON Order to buy (sell) would not be eligible to trade against an Aggressing Order or Aggressing Quote to sell (buy): (i) At a price equal to or above (below) any orders or quotes to sell (buy) that are displayed at a price equal to or below (above) the working price of such AON Order; or (ii) at a price above (below) any orders or quotes to sell (buy) that are not displayed and that have a working price below (above) the working price of such AON Order. This proposed rule text is new functionality for AON Orders that is designed to protect the priority of resting orders and quotes and is based on how the MTS Modifier functions on the cash equity market, as described in Rule 7.31–E(i)(3)(C) and its subparagraphs (i) and (ii).

• Proposed Rule 6.62P–O(d)(3)(E) would provide that if a resting AON Order to buy (sell) becomes an Aggressing Order it would trade as provided in paragraph (d)(3)(B) of this Rule; however, other resting orders or quotes to buy (sell) ranked Priority 3—Non-Display Orders that become Aggressing Orders or Aggressing Quotes at the same time as the resting AON Order would be processed before the AON Order. This is proposed new functionality and is designed to promote clarity in Exchange rules that if multiple orders ranked Priority 3—Non-Display Orders, including AON and non-AON Orders, become Aggressing Orders or Aggressing Quotes at the same time, the AON Order would not be eligible trade until the other orders ranked Priority 3-Non-Display Orders have been processed, even if they have later working times. The Exchange believes that it would be consistent with the conditional nature of AON Orders for other same-side non-displayed orders to have a trading opportunity before the AON Order.

• Proposed Rule 6.62P–O(d)(3)(F) would provide that an AON Order may be designated with a Non-Display Remove Modifier and if so designated, a resting AON Order to buy (sell) that can trade with an ALO Order or Day ISO ALO Order to sell (buy) would trade as the liquidity-taking order. This proposed functionality would be new for options trading and is based on the Non-Display Remove Modifier available on the cash equity market, as described in Rules 7.31–E(d)(2)(B) and 7.31–E(e)(1)(C).

Stop Order. Stop Orders are currently defined in Rule 6.62–O(d)(1). The Exchange proposes to use Pillar terminology to describe Stop Orders in proposed Rule 6.62P–O(d)(4). Proposed Rule 6.62P–O(d)(4) would provide that a Stop Order is an order to buy (sell) a particular option contract that becomes a Market Order (or is ''elected'') when the Exchange BB (BO) or the most recent consolidated last sale price reported after the order was placed in the Consolidated Book (the ''Consolidated Last Sale'') (either, the ''trigger'') is equal to or higher (lower) than the specified ''stop'' price. Because a Stop Order becomes a Market Order when it is elected, the Exchange proposes that when it is elected, it would be cancelled if it does not meet the validations specified in proposed Rule 6.62P–O(a)(1)(A) and if not cancelled, it would be assigned a Trading Collar.

Proposed Rule 6.62P–O(d)(4)(A) would provide that a Stop Order would be assigned a working time when it is received but would not be ranked or displayed in the Consolidated Book until it is elected and that once converted to a Market Order, the order would be assigned a new working time and be ranked Priority 1- Market Orders. The original working time assigned to a Stop Order would be used to rank multiple Stop Orders elected at the same time.

Proposed Rule 6.62P–O(d)(4)(B) would specify additional events that are designed to limit when a Stop Order may be elected so that a Market Order does not trade during a period of pricing uncertainty:

• Proposed Rule 6.62P–O(d)(4)(B)(i) would provide that if not elected on arrival, a Stop Order that is resting would not be eligible to be elected based on a Consolidated Last Sale unless the Consolidated Last Sale is equal to or in between the NBBO. This proposed rule text provides additional transparency of when a resting Stop Order would be eligible to be elected.

• Proposed Rule 6.62P–O(d)(4)(B)(ii) would provide that a Stop Order would not be elected if the NBBO is crossed.

• Proposed Rule 6.62P–O(d)(4)(B)(iii) would provide that after a Limit State or Straddle State is lifted, the trigger to elect a Stop Order would be either the Consolidated Last Sale received after such state was lifted or the Exchange BB (BO).[30]

Stop Limit Order. Stop Limit Orders are currently defined in Rule 6.62–O(d)(2). The Exchange proposes to use Pillar terminology to describe Stop Limit Orders in proposed Rule 6.62P–O(d)(5). Proposed Rule 6.62P–O(d)(5) would provide that a Stop Limit Order is an order to buy (sell) a particular option contract that becomes a Limit Order (or is ''elected'') when the Exchange BB (BO) or the Consolidated Last Sale (either, the ''trigger'') is equal to or higher (lower) than the specified ''stop'' price.[31] As further proposed, a Stop Limit Order to buy (sell) would be rejected if the stop price is higher (lower) than its limit price. Because a Stop Limit Order becomes a Limit Order when it is elected, the Exchange proposes that when it is elected, it would be cancelled if it fails Limit Order Price Protection or a Price Reasonability Check and if not cancelled, it would be assigned a Trading Collar.[32]

Proposed Rule 6.62P–O(d)(5)(A) would provide that a Stop Limit Order would be assigned a working time when it is received but would not be ranked or displayed in the Consolidated Book until it is elected and that once converted to a Limit Order, the order would be assigned a new working time and be ranked Priority 2—Display Orders.

Proposed Rule 6.62P–O(d)(5)(B) would specify additional events that are designed to limit when a Stop Limit Order may be elected so that a Limit

[30] Rule 6.65A(a)(2) currently provides that the Exchange will not elect Stop Orders when the underlying NMS stock is either in a Limit State or a Straddle State, which would continue to be applicable on Pillar. The Exchange proposes a non-substantive amendment to Rule 6.65A(a)(2) to add a cross-reference to proposed Rule 6.62P–O(d)(4).

[31] The term ''Consolidated Last Sale'' is defined in proposed Rule 6.62P–O(d)(4).

[32] *See* discussion *infra,* regarding proposed Rule 6.41P–O and Price Reasonability Checks.

Order would not have a possibility of trading or being added to the Consolidated Book during a period of pricing uncertainty.

• Proposed Rule 6.62P–O(d)(5)(B)(i) would provide that if not elected on arrival, a Stop Limit Order that is resting would not be eligible to be elected based on a Consolidated Last Sale unless the Consolidated Last Sale is equal to or in between the NBBO.

• Proposed Rule 6.62P–O(d)(5)(B)(ii) would provide that a Stop Limit Order would not be elected if the NBBO is crossed.

Orders with Instructions Not to Route. Currently, the Exchange defines non-routable orders in Rule 6.62–O as a PNP Order (which includes a Repricing PNP Order or RPNP) (current Rule 6.62–O(p)), a Liquidity Adding Order (''ALO'') (which includes a Repricing ALO (''RALO'') (current Rule 6.62–O(t)); a PNP-Blind Order (current Rule 6.62–O(u)); and a PNP-Light Order (Rule 6.62–O(v)). The Exchange also defines the PNP Plus Order (current Rule 6.62–O(y)), which is available for Electronic Complex Orders, and Intermarket Sweep Orders (current Rule 6.62–O(aa)).

The Exchange separately defines non-routable quotes in Rule 6.37A–O as a Market Maker—Light Only Quotation (''MMLO'') (current Rule 6.37A–O(a)(3)(A)); a Market Maker—Add Liquidity Only Quotation (''MMALO'') (current Rule 6.37A–O(a)(3)(B)); and a Market Maker—Repricing Quotation (''MMRP'') (current Rule 6.37A–O(a)(3)(C)).

On Pillar, the Exchange proposes to streamline the non-routable order types and quotes that would be available for options trading, use terminology that is similar to how non-routable orders are described for cash equity trading as described in Rule 7.31–E(e), and describe the functionality that would be applicable to both orders and quotes in proposed Rule 6.62P–O(e). As described in greater detail below, proposed Rule 6.37AP–O governing Market Maker Quotations would no longer define how quotations would function. Instead, that rule would specify that Market Maker quotes must be designated as either a Non-Routable Limit Order or ALO Order. On Pillar, the Exchange would no longer offer functionality based on the PNP-Blind Order, PNP-Light Order, or MMLO.

Non-Routable Limit Order. Proposed Rule 6.62P–O(e)(1) would define the Non-Routable Limit Order. This proposed order type incorporates functionality currently available in both the existing PNP and RPNP order types, as defined in Rule 6.62–O, and the existing MMRP quotation type, as defined in Rule 6.37A–O(a)(3)(C), and uses Pillar terminology.

Proposed Rule 6.62P–O(e)(1) would provide that a Non-Routable Limit Order is a Limit Order or quote that does not route and may be designated Day or GTC and would further provide that a Non-Routable Limit Order with a working price different from the display price would be ranked Priority 3-Non-Display Orders and a Non-Routable Limit Order with a working price equal to the display price would be ranked Priority 2-Display Orders. This proposed rule uses Pillar terminology similar to how a Non-Routable Limit Order is described for the Exchange's cash equity market in Rules 7.31–E(e)(1) and 7.31–E(e)(1)(B).

Proposed Rule 6.62P–O(e)(1)(A) would provide that a Non-Routable Limit Order would not be displayed at a price that would lock or cross an Away Market NBBO and that a Non-Routable Limit Order to buy (sell) would trade with orders or quotes to sell (buy) in the Consolidated Book priced at or below (above) the Away Market NBO (NBB).

Proposed Rule 6.62P–O(e)(1)(A)(i) would provide that a Non-Routable Limit Order can be designated to be cancelled if it would be displayed at a price other than its limit price. The proposed option to cancel a Non-Routable Limit Order is based on how a PNP Order currently functions. The Exchange proposes a substantive difference that if an OTP Holder or OTP Firm opts to cancel instead of reprice a Non-Routable Limit Order, such order would be cancelled if it could not be displayed at its limit price, which could be because the order would be repriced to display at a price that would not lock or cross an Away Market NBBO or because it would be repriced due to Trading Collars.[33]

Proposed Rule 6.62P–O(e)(1)(A)(ii) would provide that if not designated to cancel, if the limit price of a Non-Routable Limit Order to buy (sell) would lock or cross an Away Market NBO (NBB), it would be repriced to have a working price equal to the Away Market NBO (NBB) and a display price one MPV below (above) that NBO (NBB). Accordingly, the proposed Non-Routable Limit Order, if not designated to cancel, would reprice in the same manner as an RPNP order or MMRP quotation.

The Exchange proposes new functionality for the Non-Routable Limit Order as compared to either the RPNP Order or the Non-Routable Limit Order on the Exchange's cash equity market. Specifically, proposed Rule 6.62P–O(e)(1)(B) would provide that the display price of a resting Non-Routable Limit Order to buy (sell) that has been repriced would be repriced higher (lower) only one additional time.[34] If after that repricing, the display price could be repriced higher (lower) again, the order can be designated to either remain at its last working price and display price or be cancelled, provided that a resting Non-Routable Limit Order that is a quote cannot be designated to be cancelled.[35]

The Exchange notes that this designation to cancel is separate from the designation to cancel if it cannot be displayed at its limit price. If a Non-Routable Limit Order is designated to cancel if it cannot be displayed at its limit price, this second cancellation designation would not be needed as the order would have already been cancelled. Rather, this second cancellation designation is applicable only to a resting Non-Routable Limit Order that has been designated to reprice on arrival and was repriced before it was displayed on the Consolidated Book, and provides OTP Holders and OTP Firms with an option to cancel a resting order if market conditions were such that a resting order could have been repriced again, *e.g.,* the contra-side Away Market NBBO changes. To assist Market Makers in maintaining quotes in their assigned series, the Exchange proposes that this second cancellation designation would not be available to Market Makers for their quotes.

Proposed Rule 6.62P–O(e)(1)(B)(i) would provide that if the limit price of the resting Non-Routable Limit Order to

[33] Because Trading Collars would be applicable to Non-Routable Limit Orders, the Exchange does not propose to cancel an incoming Non-Routable Limit Order if its price is more than a configurable number of MPVs outside its initial display price, which is how an RPNP currently functions, and therefore would not include functionality based on Rule 6.62–O(p)(1)(B) in the proposed Pillar rules.

[34] For example, on arrival, a Non-Routable Limit Order to buy (sell) with a limit price higher (lower) than the NBO (NBB), would have a display price one MPV below (above) the NBO (NBB) and a working price equal to the NBO (NBB). If the Away Market NBO (NBB) reprices higher (lower), the resting Non-Routable Limit Order to buy (sell) would similarly be repriced higher (lower). If the NBO (NBB) adjusts higher (lower) again, the resting Non-Routable Limit Order would not be adjusted again.

[35] The working time of a Non-Routable Limit Order would be adjusted as described in proposed Rule 6.76P–O(f)(2), which would be applicable to any scenario when the working time of an order may change, including a Non-Routable Limit Order. Similar to how the Pillar rules function on the Exchange's cash equity market, the Exchange does not propose to separately describe how the working time of an order changes in proposed Rule 6.62P–O.

buy (sell) that has been repriced no longer locks or crosses the Away Market NBO (NBB), it would be assigned a working price and display price equal to its limit price. This proposed rule text is based on Rule 7.31–E(e)(1)(A)(iv).

Proposed Rule 6.62P–O(e)(1)(B)(ii) would provide that the working price of a resting Non-Routable Limit Order to buy (sell) that has been repriced would be adjusted to be equal to its display price if the Away Market NBO (NBB) is equal to or lower (higher) than its display price. This proposed rule is based in part on how an RPNP reprices (as described in Rule 6.62–O(p)(1)(A)(i)) and uses Pillar terminology. The proposed rule would further provide that once the working price and display price of a Non-Routable Limit Order to buy (sell) are the same, the working price would be adjusted higher (lower) only if the display price of the order is adjusted.[36]

Proposed Rule 6.62P–O(e)(1)(C) would provide that a Non-Routable Limit Order may be designated with a Non-Display Remove Modifier and if so designated, a Non-Routable Limit Order to buy (sell) with a working price, but not display price, equal to the working price of an ALO Order or Day ISO ALO to sell (buy) would trade as the liquidity taker against such order. This functionality is based on the Non-Display Remove Modifier available for cash equity trading, as described in Rule 7.31–E(e)(1)(C), and would be new for options trading on Pillar.

Finally, proposed Rule 6.62P–O(e)(1)(D) would provide that the designation to cancel a Non-Routable Limit Order would not be applicable in an Auction and such order will participate in an Auction at its limit price. This proposed rule text promotes clarity and transparency that a Non-Routable Limit Order would be eligible to participate in an Auction, but that it would be repriced to its limit price for participation in such Auction.

ALO Order. Proposed Rule 6.62P–O(e)(2) would define an ALO Order as a Limit Order or quote that is a Non-Routable Limit Order that would not remove liquidity from the Consolidated Book. This proposed order type incorporates functionality similar to both the existing ALO and RALO order types, as defined in Rule 6.62–O, and the existing MMALO quotation type, as defined in Rule 6.37A–O(a)(3)(B). Unless otherwise specified in proposed Rule 6.62P–O(e)(2), an ALO Order would function as a Non-Routable Limit Order, including that it would participate in an Auction at its limit price.

Proposed Rule 6.62P–O(e)(2)(A) would provide that an ALO Order would not be displayed at a price that would lock or cross an Away Market NBBO, would lock or cross displayed interest in the Consolidated Book, or would cross non-displayed interest in the Consolidated Book. Because an ALO Order would never remove liquidity, this proposed rule text ensures that such order would not be displayed at a price that would lock or cross displayed interest either on the Exchange or an Away Market, and would not be displayed at a price that crosses non-displayed interest in the Consolidated Book.

Proposed Rule 6.62P–O(e)(2)(A)(i) would provide that an ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price. An ALO Order with this designation to cancel would function similarly to a Liquidity Adding Order as defined in Rule 6.62–O(t) and uses Pillar terminology.

Proposed Rule 6.62P–O(e)(2)(A)(ii) would provide that an ALO Order to buy (sell) would be displayed at its limit price if it locks non-displayed orders or quotes to sell (buy) on the Consolidated Book. Because an ALO Order would not be repriced in this scenario, this functionality would be the same regardless of whether the order includes a designation to cancel.

Proposed Rule 6.62P–O(e)(2)(A)(iii) would provide that an ALO Order to buy (sell) would not consider an AON Order or an order with an MTS Modifier to sell (buy) for purposes of determining whether it needs to be repriced or cancelled. This proposed rule is designed to promote transparency that a resting contra-side order with conditional instructions, *i.e.,* an AON Order or an order with an MTS Modifier, would not have any bearing on whether an Aggressing ALO Order would need to be repriced. Accordingly, an ALO Order would neither trade as the liquidity taker with such orders (even if it could satisfy their size condition) and could be displayed at a price that would lock or cross the price of such orders. Once the ALO Order is resting on the Consolidated Book, the Exchange would reevaluate the orders on the Consolidated Book. For example, if the ALO Order could satisfy the size condition of the resting AON Order, the resting AON Order would become the Aggressing Order and would trade as the liquidity taker with such resting ALO Order.

Proposed Rule 6.62P–O(e)(2)(B) would describe how an ALO Order would be processed if it is not designated to cancel, as follows:

- If the limit price of an ALO Order to buy (sell) would lock or cross displayed orders or quotes to sell (buy) on the Consolidated Book, it would be repriced to have a working price and display price one MPV below (above) the lowest (highest) priced displayed order or quote to sell (buy) on the Consolidated Book (proposed Rule 6.62P–O(e)(2)(B)(i));
- If the limit price of an ALO Order to buy (sell) would lock or cross an Away Market NBO (NBB), it would be repriced to have a working price equal to the Away Market NBO (NBB) and a display price one MPV below (above) the NBO (NBB) (proposed Rule 6.62P–O(e)(2)(B)(ii)); or
- If the limit price of an ALO Order to buy (sell) would cross non-displayed orders or quotes[37] on the Consolidated Book, it would be repriced to have a working price and display price equal to the lowest (highest) priced non-displayed order or quote to sell (buy) on the Consolidated Book (proposed Rule 6.62P–O(e)(2)(B)(iii).

Because an ALO would never be a liquidity-taking order, the above-described repricing scenarios provide clarity and transparency regarding how an ALO Order would be repriced to prevent either trading with interest on the Consolidated Book or routing to an Away Market. The proposed option to reprice is based in part on how a RALO currently functions, as described in Rule 6.62–O(t)(1)(A).

Proposed Rule 6.62P–O(e)(2)(C) would provide that the display price of a resting ALO Order to buy (sell) that has been repriced would be repriced higher (lower) only one additional time and that if, after that repricing, the display price could be repriced higher (lower) again, the order can be designated to either remain at its last working price and display price or be cancelled, provided that a resting ALO Order that is a quote cannot be designated to be cancelled. This proposed functionality would be new to Pillar and is based on how the proposed Non-Routable Limit Order would function, as described above.

[36] For example, if the Away Market NBO is 1.05 and the Exchange receives a Non-Routable Limit Order to buy priced at 1.10, it would be assigned a display price of 1.00 and a working price of 1.05. If the Away Market NBO adjusts to 1.00, the working price of the Non-Routable Limit Order to buy would be adjusted to 1.00 to be equal to its display price. However, if the Away Market NBO moves back to 1.05, the Non-Routable Limit Order's working price would not adjust again to 1.05 and would stay at 1.00.

[37] For example, a contra-side Market Maker quote designated as a Non-Routable Limit Order could have a non-displayed working price.

Proposed Rule 6.62P–O(e)(2)(C)(i) would provide that if the limit price of an ALO Order to buy (sell) that has been repriced no longer locks or crosses displayed orders or quotes in the Consolidated Book, locks or crosses the Away Market NBBO, or crosses non-displayed orders or quotes in the Consolidated Book, it would be assigned a working price and display price equal to its limit price. This proposed rule text is similar to proposed Rule 6.62P–O(e)(1)(B)(i) for Non-Routable Limit Orders, with differences to reflect the additional circumstances when an ALO Order would be repriced based off of contra-side displayed or non-displayed interest in the Consolidated Book.

Proposed Rule 6.62P–O(e)(2)(D) would provide that the working price of a resting ALO Order to buy (sell) that has been repriced would be adjusted to be equal to its display price (and would not be adjusted again unless the display price of the order is adjusted) if:

- The Away Market NBO (NBB) re-prices to be equal to or lower (higher) than the display price of the resting ALO Order to buy (sell) (proposed Rule 6.62P–O(e)(2)(D)(i)); or
- an ALO Order or Day ISO ALO to sell (buy) is displayed on the Consolidated Book at a price equal to the working price of the resting ALO Order to buy (sell) (proposed Rule 6.62P–O(e)(2)(D)(ii)).

This proposed rule text is similar to proposed Rule 6.62P–O(e)(1)(C) for Non-Routable Limit Orders, with differences to reflect the additional circumstances when an ALO Order would be repriced as a result of contra-side interest on the Consolidated Book. Specifically, the Exchange proposes that for an ALO Order that has been repriced and has a non-displayed working price, if the Exchange receives a contra-side ALO Order (or Day ISO ALO) with a limit price that is equal to or crosses the working price of the resting ALO Order, the working price of the resting ALO Order would be adjusted to be equal to its display price. This proposed functionality would reduce the potential for two contra-side ALO Orders to have working prices that are locked on the Consolidated Book.

Proposed Rule 6.62P–O(e)(2)(E) would provide that when the working price and display price of an ALO Order to buy (sell) are the same, the working price would be adjusted higher (lower) only if the display price of the order is adjusted. This proposed functionality would be new for Pillar.

Proposed Rule 6.62P–O(e)(2)(F) would provide that the ALO designation would be ignored for ALO Orders that participate in an Auction. This proposed rule is based on Rule 7.31–E(e)(2)(A), which similarly provides that an ALO Order can participate in an auction and that its ALO designation would be ignored. This is also new functionality for options because currently, the Exchange rejects ALOs if entered outside of Core Trading Hours or during a trading halt and if resting, are cancelled during a trading halt.

Proposed Rule 6.62P–O(e)(2)(G) would provide that an ALO Order cannot be designated with a Non-Display Remove Modifier. Because an ALO Order is a type of Non-Routable Limit Order, this proposed rule promotes clarity that the Non-Display Remove Modifier would not be available for an ALO Order.

Intermarket Sweep Order (''ISO''). ISOs are currently defined in Rule 6.62–O as a Limit Order for an options series that instructs the Exchange to execute the order up to the price of its limit, regardless of the Away Market Protected Quotations [38] and that ISOs may only be entered with a time-in-force of IOC, and the entering OTP Holder must comply with the provisions of 6.92–O(a)(8). Proposed Rule 6.62P–O(e)(3) would similarly provide than an ISO is a Limit Order that does not route and meets the requirements of Rule 6.92–O(a)(8).

On Pillar, the Exchange will continue to offer the same type of ISO functionality, and proposes to add the ability for an OTP Holder or OTP Firm to designate an ISO with a Day time-in-force designation and designate a Day ISO as ALO, which functionality is available on the Exchange's cash equity market as described in Rule 7.31–E(e)(3). The Exchange proposes to describe the functionality for each type of ISO separately.

- *IOC ISO.* Proposed Rule 6.62P–O(e)(3)(A) would define an IOC ISO as an ISO designated IOC to buy (sell) that would be immediately traded with orders and quotes to sell (buy) in the Consolidated Book up to its full size and limit price and may trade through Away Market Protected Quotations and any untraded quantity of an IOC ISO will be immediately and automatically cancelled. This proposed rule is based on Rule 7.31–E(e)(3)(B) and uses Pillar terminology to describe functions that are currently available for options trading.
- *Day ISO.* Proposed Rule 6.62–O(e)(3)(B) would define a Day ISO as an ISO designated Day to buy (sell) that, if marketable on arrival, would be immediately traded with orders and quotes to sell (buy) in the Consolidated Book up to its full size and limit price and may trade through Away Market Protected Quotations and that any untraded quantity of a Day ISO would be displayed at its limit price and may lock or cross Away Market Protected Quotations at the time the Day ISO is received by the Exchange. This proposed functionality would be new on the Exchange for options trading and is based on the Day ISO functionality available on the Exchange's cash equity market, as described in Rule 7.31–E(e)(3)(C). However, the availability of the Day time-in-force designation for ISOs would not be new for options trading, as such orders are currently available on other options exchanges.[39] The proposed Day ISO is also consistent with current Rule 6.95–O(b)(3), which describes an exception to the prohibition on locking or crossing a Protected Quotation if the Member simultaneously routed an ISO to execute against the full displayed size of any locked or crossed Protected Bid or Protected Offer.[40] Although the Exchange has not previously availed itself of this exception, this exception to locking and crossing Protected Bids and Protected Offers would only be needed if an ISO is designated as Day and therefore would be displayed at a price that would lock or cross a Protected

[38] The terms ''Protected Bid,'' ''Protected Offer,'' and ''Quotation'' are defined in Rule 6.92–O(a)(15) and (16) and the term ''Away Market'' is defined in Rule 1.1. Accordingly, Away Market Protected Quotations refer to Protected Bids and Protected Offers that are disseminated pursuant to the OPRA Plan and are the Best Bid and Best Offer displayed by an Eligible Exchange, as those terms are defined in Rule 6.92–O.

[39] *See* Nasdaq Options 3, Section 7(a)(7) (''ISOs may have any time-in-force designation. . . .'') and CBOE Rules 5.30(a)(2) and (3). *See also* Cboe US Options Fix Specifications, dated June 15, 2021, Section 4.4.7, available here: *http://cdn.cboe.com/resources/membership/US_Options_FIX_Specification.pdf,* which references how a Day ISO would be processed under specified circumstances.

[40] The Commission has previously stated that the requirements in the Options Linkage Plan relating to Locked and Crossed Markets are ''virtually identical to those applicable to market centers for NMS stock under Regulation NMS.'' *See also* Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362, 39368 (August 6, 2009) (Order approving Options Linkage Plan). Accordingly, guidance relating to the ISO exception for locked and crossed markets for NMS stocks that specifically contemplate use of Day ISOs is also applicable to options trading. *See* Responses to Frequently Asked Questions Concerning Rule 611 and Rule 610 of Regulation NMS, FAQ 5.02 (''The ISO exception to the SRO lock/cross rules, in contrast, requires that ISOs be routed to execute against all protected quotations with a price that is *equal* to the display price (*i.e.,* those protected quotations that would be locked by the displayed quotation), as well as all protected quotations with prices that are better than the display price (*i.e.,* those protected quotations that would be crossed by the displayed quotation).'' Consistent with this guidance, the Exchange implemented Rule 6.95–O(b)(3). *See also* Cboe Rule 5.67(b)(3), *and* Nasdaq Options 5, Section 3(b)(3).

Quotation; an IOC ISO would never be displayed and therefore this existing exception would not be applicable to such orders.

• *Day ISO ALO.* Proposed Rule 6.62P–O(e)(3)(C) would define a Day ISO ALO as a Day ISO with an ALO modifier. This proposed order type is based in part on the Day ISO ALO currently available on the Exchange's cash equity market, as described in Rule 7.31–E(e)(3)(D), but with differences to reflect how the order type would function on the Exchange's options market, as described above. As proposed, on arrival, a Day ISO ALO to buy (sell) may lock or cross Away Market Protected Quotations at the time of arrival of the Day ISO ALO but would not remove liquidity from the Consolidated Book. A Day ISO ALO to buy (sell) can be designated to be cancelled if it would be displayed at a price other than its limit price. Proposed Rule 6.62P–O(e)(3)(C)(i) would provide that if not designated to cancel, a Day ISO ALO that would lock or cross orders and quotes on the Consolidated Book would be repriced as specified in proposed Rule 6.62P–O(e)(2)(B). Proposed Rule 6.62P–O(e)(3)(C)(ii) would provide that once resting, a DAY ISO ALO would be processed as an ALO Order as specified in proposed Rule 6.62P–O(e)(2)(C)–(G).

Complex Orders. Complex Orders are defined in Rule 6.62–O(e). The Exchange proposes to define Complex Orders for Pillar in proposed Rule 6.62P–O(f) based on Rule 6.62–O(e) and its sub-paragraphs (1) and (2) without any substantive differences. The Exchange proposes to add clarifying text that the different options series in a Complex Order are also referred to as the ''legs'' or ''components'' of the Complex Order. The Exchange also proposes that proposed Rule 6.62P–O(f) would provide that a Complex Order would be any order involving the simultaneous purchase and/or sale of ''two or more options series in the same underlying security,'' and not use the modifier ''different'' before the phrase ''more option series.'' The Exchange believes that the word ''different'' is redundant and unnecessary in this context. In addition, proposed Rule 6.62P–O(f)(1) and (2) would not reference mini-options contracts, which no longer trade on the Exchange.

Cross Orders. Currently, the only electronically-entered cross orders available on the Exchange are Qualified Contingent Cross Orders, which are defined in Rule 6.62–O(bb) and Commentary .02 to Rule 6.62–O. In addition, Rule 6.90–O describes how Qualified Contingent Cross Orders are processed. The Exchange proposes to define the term ''Cross Orders'' on Pillar in proposed Rule 6.62P–O(g). At this time, the only Cross Orders that would be available on Pillar for electronic entry would be Qualified Contingent Cross (''QCC'') Orders. As proposed, QCC Orders on Pillar would function identically to how Qualified Contingent Cross Orders function on the OX system, and for purposes of the rules governing trading on Pillar, the Exchange proposes to merge language from two rules relating to QCC Orders into a single rule, proposed Rule 6.62P–O(g), using Pillar terminology. Proposed Rule 6.62P–O(g) and (g)(1) would describe rules generally applicable to electronically-entered Cross Orders, including QCC Orders, and proposed Rule 6.62P–O(g)(2) would address requirements specific to QCC Cross Orders.

Proposed Rule 6.62P–O(g) would provide that ''Cross Orders'' would be two-sided order messages with instructions to match the identified buy-side with the identified sell-side at a specified price, which could either be designated as a limit price or at the market (''cross price'').[41] The proposed rule would further provide that a Cross Order that is not rejected per proposed Rule 6.62P–O(g)(1) would immediately trade in full at its cross price, would not route, and may be entered with an MPV of $0.01 regardless of the MPV of the options series and that Cross Orders may be entered by Floor Brokers from the Trading Floor or routed to the Exchange from off-Floor.

Proposed Rule 6.62P–O(g)(1) would provide that a Cross Order would be rejected if received when the NBBO is crossed or if it would be traded at a cross price that (i) is at the same price as a displayed Customer order on the Consolidated Book and (ii) is not at or between the NBBO. This proposed rule is based on Rule 6.90–O without any differences.

Proposed Rule 6.62P–O(g)(1) would further set forth how a Cross Order designated to trade at the market would be priced. As proposed, a Cross Order with a cross price at the market would execute at the midpoint of the NBBO; provided that:

• If there is no NBB, a zero bid would be used (proposed Rule 6.62P–O(g)(1)(A));

• if there is displayed Customer interest priced equal to the NBB, NBO or both, the midpoint would be based on the BBO improved by $0.01 for the side(s) containing displayed Customer interest (proposed Rule 6.62P–O(g)(1)(B));

• if there is no NBO, such order would be rejected (proposed Rule 6.62P–O(g)(1)(C)); or

• if the midpoint of the NBBO is in sub-pennies, the order would trade at the midpoint of the NBBO rounded down to the MPV for the series (proposed Rule 6.62P–O(g)(1)(D)).

This proposed rule text is designed to promote clarity and transparency in Exchange rules regarding how a Cross Order ''at the market'' would execute in circumstances when there is no NBB or NBO or there is displayed Customer interest equal to the NBBO.

Proposed Rule 6.62P–O(g)(2) would define QCC Orders, which would be the only Cross Orders available on Pillar at this time. As proposed, a QCC Order must be comprised of an originating order to buy or sell at least 1,000 contracts that is identified as being part of a qualified contingent trade coupled with a contra-side order or orders totaling an equal number of contracts. This proposed rule text is based on Rule 6.62–O(bb) with a non-substantive difference that the Pillar rule would not reference mini-options contracts, which no longer trade on the Exchange.

Proposed Rule 6.62P–O(g)(2)(A) and subparagraphs (i)–(vi) would define a ''qualified contingent trade'' and is based on Commentary .02 and sub-paragraphs (a)–(f) to Rule 6.62–O without any substantive differences.

Proposed Rule 6.62P–O(g)(2)(B) would specify rules governing QCC Orders entered from the Trading Floor, which can be entered only by Floor Brokers, and is based on Commentary .01 to Rule 6.90–O. The proposed rule would provide that while on the Trading Floor, only Floor Brokers can enter QCC Orders and that Floor Brokers may not enter QCC Orders for their own account, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion (each a ''prohibited account''). As further proposed, when executing such orders, Floor Brokers would not be subject to Rule 6.47–O regarding ''Crossing'' orders. Floor Brokers must maintain books and records demonstrating that each QCC Order entered from the Floor was not entered for a prohibited account. Any QCC Order entered from the Floor that does not have a corresponding record required by this paragraph will be deemed to have been entered for a prohibited account in violation of this Rule.

[41] The Exchange does not currently offer Cross Orders on its cash equity market. This proposed rule text uses Pillar terminology that is based in part on NYSE Chicago Rule 7.31(g).

Proposed Rule 6.62P–O(g)(2)(C) would specify rules governing QCC Orders entered off-Floor and that OTP Holders must maintain books and records demonstrating that each such order was so routed. This proposed rule is based on Commentary .02 to Rule 6.90–O without any substantive differences.

To promote clarity, the Exchange proposes to amend Rule 6.90–O to specify that the rule would not be applicable to trading on Pillar.

Orders Available Only in Open Outcry. The Exchange proposes to add to Rule 6.62P–O(h) orders that are available only in open outcry, most of which are currently defined in Rule 6.62–O.

First, proposed Rule 6.62P–O(h)(1) would codify an existing order type, the Clear-the-Book (''CTB'') Order, which is currently only described in a Regulatory Bulletin.[42] The proposed definition would describe the CTB Order, which would be an order type available in open outcry that would interface with the Consolidated Book, and therefore with Pillar. As proposed, a CTB Order would be a Limit IOC Order that may be entered only by a Floor Broker, subsequent to executing an order in open outcry, that is approved by a Trading Official (the ''TO Approval''). The CTB Order would be eligible to trade only with contra-side orders and quotes that were resting in the Consolidated Book prior to the TO Approval. In addition, proposed Rule 6.62P–O(h)(1)(A)–(C) would provide that:

- A CTB Order to buy (sell) would trade with contra-side orders and quotes with a display price below (above) the limit price of the CTB Order (proposed Rule 6.62P–O(h)(1)(A));
- A CTB Order to buy (sell) would trade with contra-side orders and quotes that have a display price and working price equal to the limit price of the CTB Order only if there is displayed Customer sell (buy) interest at that price, in which case, the CTB Order to buy (sell) would trade with the displayed Customer interest to sell (buy) and any non-Customer interest to sell (buy) with a working time earlier than the latest-arriving displayed Customer interest to sell (buy) (proposed Rule 6.62P–O(h)(1)(B)); and
- Any unexecuted portion of the CTB Order would cancel after trading with all better-priced interest and eligible same-priced interest on the Consolidated Book (proposed Rule 6.62P–O(h)(1)(C)).

Currently, CTB Orders only trade with displayed Customer interest and any same-priced displayed non-Customer interest ranked ahead of such interest in time priority, but do not trade with better-priced displayed non-Customer interest. In Pillar, per Rule 6.62P–O(h)(1)(B), CTB Orders would trade with displayed non-Customer interest priced better than the latest-arriving displayed Customer interest (*i.e.,* a CTB order buying with a $1.00 limit would now trade with any displayed interest offered at $0.99). The Exchange believes that this proposed change would increase execution opportunities and achieve the goal of a CTB Order, which is to clear priority on the Consolidated Book at the time of the TO Approval.

In addition, proposed Rule 6.62P–O(h)(1)(D) would codify existing regulatory responsibilities of Floor Brokers utilizing CTB Orders to submit such orders in a timely manner after receiving TO Approval and would also provide that because CTB Orders are non-routable, Floor Brokers would be obligated to route orders to better-priced interest to Away Markets per Rule 6.94–O.[43]

The Exchange also proposes to include in Rule 6.62P–O additional open outcry order types that are currently defined in Rule 6.62–O:

- Proposed Rule 6.62P–O(h)(2) would define ''Facilitation Order'' and is based on the Rule 6.62–O(j) definition of Facilitation Order without any differences.
- Proposed Rule 6.62P–O(h)(3) would define ''Mid-Point Crossing Order'' and is based on the Rule 6.62–O(q) definition of Mid-Point Crossing Order without any differences.
- Proposed Rule 6.62P–O(h)(4) would define ''Not Held Order'' and is based on the Rule 6.62–O(f) definition of Not Held Order without any differences.
- Proposed Rule 6.62P–O(h)(5) would define ''Single Stock Future (''SSF'')/Option Order'' and is based on the Rule 6.62–O(i) definition of Single Stock Future (''SSF'')/Option Order without any differences.
- Proposed Rule 6.62P–O(h)(6)(A) would define a ''Stock/Option Order'' and is based on the Rule 6.62–O(h)(1) definition of Stock/Option Order without any differences.
- Proposed Rule 6.62P–O(h)(6)(B) and subparagraphs (i) and (ii) would define a ''Stock/Complex Order'' and is based on the Rule 6.62–O(h)(2) definition of Stock/Complex Order with its sub-paragraphs without any differences.

The Exchange proposes that after the transition to Pillar, the following open outcry order types, which are currently described in Rule 6.62–O but are not used by Floor Brokers, would not be added to proposed Rule 6.62P–O governing orders and modifiers: One cancels the other (OCO) Order and Stock Contingency Order.

Additional Order Instructions and Modifiers. The Exchange proposes to specify the additional order instructions and modifiers that would be available in Pillar in proposed Rule 6.62P–O(i).

Proactive if Locked/Crossed Modifier. Proposed Rule 6.62P–O(i)(1) would provide that a Limit Order that is displayed and eligible to route and designated with a Proactive if Locked/Crossed Modifier would route to an Away Market if the Away Market locks or crosses the display price of the order and that if any quantity of the routed order is returned unexecuted, the order would be displayed in the Consolidated Book. This would be new functionality for options trading on the Exchange and is based on the Proactive if Locked/Crossed Modifier available on the Exchange's cash equity platform, as described in Rule 7.31–E(i)(1) without any differences.

Self-Trade Prevention (''STP'') Modifier. Self-Trade Prevention (''STP'') Modifiers are currently defined in Commentary .01 to Rule 6.76A–O and are available only for Market Maker orders and quotes. On Pillar, the Exchange proposes to expand the availability of STP to all orders and quotes. Because STP Modifiers are an instruction that can be added to an order or quote, the Exchange proposes that for Pillar, STP Modifiers would be described in proposed Rule 6.62P–O(i)(2). This is based on the structure of the Exchange's cash equity rules, which also describe the STP Modifier in Rule 7.31–E(i).

Proposed Rule 6.62P–O(i)(2) would provide that an Aggressing Order or Aggressing Quote to buy (sell) designated with one of the STP modifiers in proposed Rule 6.62P–O(i)(2) would be prevented from trading with a resting order or quote to sell (buy) also designated with an STP modifier from the same MPID, and, if specified, any sub-identifier of that MPID and that the STP modifier on the Aggressing Order or Aggressing Quote would control the interaction between two orders and/or quotes marked with STP modifiers. In addition, STP would not be applicable during an auction or to Cross Orders or when a Complex Order legs out. This proposed rule text

[42] *See* NYSE Arca Options RB–16–04, dated February 19, 2016 (Rules of Priority and Order Protection in Open Outcry), available here: *https://www.nyse.com/publicdocs/nyse/markets/arca-options/rule-interpretations/2016/NYSE%20Arca%20Options%20RB%2016-04.pdf.*

[43] *See id.* at p. 2–3 (describing regulatory responsibilities related to CTB Orders).

is based on Commentary .01 to Rule 6.76A with non-substantive differences to use Pillar terminology.

Proposed Rule 6.62P–O(i)(2) would further provide that if the condition for a Limit Order designated FOK, an AON Order, or an order with an MTS modifier cannot be met because of STP modifiers, such order would either be cancelled or placed on the Consolidated Book, as applicable. This proposed rule text provides clarity that if a condition of an order cannot be met because of STP modifiers, the order would either cancel (*i.e.,* a Limit Order designated FOK), or be added to the Consolidated Book (*i.e.,* an AON Order or an order with an MTS modifier), and then such resting orders would function as described in Rule 6.62P–O.

The proposed rule would further provide that Aggressing Orders or Aggressing Quotes would be processed as follows:

- Proposed Rule 6.62P–O(i)(2)(A) would describe STP Cancel Newest (''STPN'') and provide that an Aggressing Order or Aggressing Quote to buy (sell) marked with the STPN modifier would not trade with resting interest to sell (buy) marked with any STP modifier from the same MPID; that the Aggressing Order or Aggressing Quote marked with the STPN modifier would be cancelled; and that the resting order or quote marked with one of the STP modifiers will remain on the Consolidated Book. This proposed rule is based on Commentary .01(a) to Rule 6.76A–O with non-substantive differences to use Pillar terminology.
- Proposed Rule 6.62P–O(i)(2)(B) would describe STP Cancel Oldest (''STPO'') and provide that an Aggressing Order or Aggressing Quote to buy (sell) marked with the STPO modifier would not trade with resting interest to sell (buy) marked with any STP modifier from the same MPID; that the resting order or quote marked with the STP modifier would be cancelled; and that the Aggressing Order or Aggressing Quote marked with the STPO modifier would be placed on the Consolidated Book. This proposed rule is based on Commentary .01(b) to Rule 6.76A–O with non-substantive differences to use Pillar terminology.
- Proposed Rule 6.62P–O(i)(2)(C) would describe STP Cancel Both (''STPC'') and provide that an Aggressing Order or Aggressing Quote to buy (sell) marked with the STPC modifier would not trade with resting interest to sell (buy) marked with any STP modifier from the same MPID and that the entire size of both orders and/or quotes would be cancelled. This proposed rule is based on Commentary .01(c) to Rule 6.76A–O with non-substantive differences to use Pillar terminology.

Minimum Trade Size Modifier. The Exchange proposes to add the Minimum Trade Size (''MTS'') Modifier, which would be new functionality for options trading on Pillar that is based on the same functionality currently available for cash equity securities trading on Pillar, as described in Rule 7.31–E(i)(3). As with the MTS Modifier for cash equity trading, the proposed MTS Modifier for options traded on Pillar would be available only for non-displayed orders. Accordingly, proposed Rule 6.62P–O(i)(3) would provide that a Limit IOC Order or Non-Displayed Limit Order may be designated with an MTS Modifier.[44]

Proposed Rule 6.62P–O(i)(3)(A) would provide that the quantity of the MTS Modifier may be less than the order quantity; however, an order would be rejected if it has an MTS Modifier quantity that is larger than the size of the order. This proposed rule is based on Rule 7.31–E(i)(3)(A) with differences only to reflect that the concept of a round lot is not applicable for options trading.

Proposed Rule 6.62P–O(i)(3)(B) would provide that one of the following instructions must be specified with respect to whether an order to buy (sell) with an MTS Modifier would trade on arrival with: (i) Orders or quotes to sell (buy) in the Consolidated Book that in the aggregate meet such order's MTS; or (ii) only individual order(s) or quote(s) to sell (buy) in the Consolidated Book that each meets such order's MTS. This proposed rule is based on Rule 7.31–E(i)(3)(B) and sub-paragraphs (i) and (ii) with only non-substantive differences to use options trading terminology (*e.g.,* Consolidated Book instead of NYSE Arca Book and reference to quotes). Otherwise, the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(C) would provide that an order with an MTS Modifier that is designated Day or GTC that cannot be executed immediately on arrival would not trade and would be ranked in the Consolidated Book. In such case, the order to buy (sell) with an MTS Modifier to buy (sell) that is ranked in the Consolidated Book would not be eligible to trade: (i) At a price equal to or above (below) any orders or quotes to sell (buy) that are displayed at a price equal to or below (above) the working price of such order with an MTS Modifier; or (ii) at a price above (below) any orders or quotes to sell (buy) that are not displayed and that have a working price below (above) the working price of such order with an MTS Modifier. This proposed rule is based on Rule 7.31–E(i)(3)(C) and sub-paragraphs (i) and (ii) with only non-substantive differences to use options trading terminology and to reflect the availability of the GTC time-in-force modifier for Non-Displayed Limit Orders. Otherwise, the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(D) would provide that an order with an MTS Modifier that is designated IOC and cannot be immediately executed would be cancelled. This proposed rule is based on Rule 7.31–E(i)(3)(D) without any differences and the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(E) would provide that a resting order to buy (sell) with an MTS Modifier would trade with individual orders and quotes to sell (buy) that each meet the MTS and that (i) if an Aggressing Order or Aggressing Quote to sell (buy) does not meet the MTS of the resting order to buy (sell) with an MTS Modifier, that Aggressing Order or Aggressing Quote would not trade with, and may trade, through such resting order with an MTS Modifier; and (ii) if a resting non-displayed order or quote to sell (buy) did not meet the MTS of a same-priced resting order or quote to buy (sell) with an MTS Modifier, a subsequently arriving order or quote to sell (buy) that meets the MTS would trade before such resting non-displayed order or quote to sell (buy) at that price. This proposed rule is based on Rule 7.31–E(i)(3)(E) and sub-paragraphs (i) and (ii) with only non-substantive differences to use options trading terminology. Otherwise, the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(F) would provide that a resting order with an MTS Modifier would be cancelled if it is traded in part or reduced in size and the remaining quantity is less than such order's MTS. This proposed rule is based on Rule 7.31–E(i)(3)(F) without any differences and the functionality would be identical on both the options and cash equity trading platforms.

In connection with proposed Rule 6.62P–O, the Exchange proposes to add the following preamble to Rule 6.62–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed

[44] For cash equity trading, the MTS Modifier is also available for an MPL Order or Tracking Order, which are non-displayed order types available on the Exchange's cash equity trading platform that would not be available for options trading on Pillar. *See* Rule 7.31–E(i)(3).

preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.62–O would not be applicable to trading on Pillar.

Proposed Rule 6.37AP–O: Market Maker Quotations

Current Rule 6.37A–O describes Market Maker quoting obligations, including defining ''quotations'' and describing the treatment to such quotations. Proposed Rule 6.37AP–O would set forth Market Maker quoting obligations under Pillar.

• First, Rule 6.37AP–O(a) would be based on the current rule and would provide that a Market Maker may enter quotations only in the issues included in its appointment. Proposed Rule 6.37AP–O(a)(1) would provide that the term ''quote'' or ''quotation'' means ''a bid or offer sent by a Market Maker that is not sent as an order'' and that ''[o]nce received by the Exchange, a subsequent quotation sent by a Market Maker replaces that Market Maker's previously displayed same-side quotation.'' This proposed text adds clarity to the existing definition that a Market Maker quote is distinct from a Market Maker order and that a subsequent quote will cancel an existing quote.

• Proposed Rule 6.37AP–O(a)(2) would provide that a Market Maker may designate a quote it sends as either a Non-Routable Limit Order or an ALO Order and such quotes would be processed in the same way as those orders are processed under proposed Rule 6.62P–O. The Exchange notes that these two quote types replace the existing quote types (*i.e.,* MMLO, MMALO and MMRP), which will no longer be offered under Pillar. Because proposed Rule 6.62P–O(e)(1) and (2) would describe the treatment of a quote designated as Non-Routable Limit Order or an ALO Order, the Exchange will not include a section in proposed Rule 6.37AP–O regarding the treatment of such quotes.

• Proposed Rule 6.37AP–O(b)—(e) would be substantively identical to current Rule 6.37A–O(b)—(e) with non-substantive differences to change the term ''shall'' to ''will.'' Proposed Commentary .01 to Rule 6.37AP–O would be substantively identical to Commentary .01 to Rule 6.37A–O, with non-substantive differences to streamline the rule text.

The Exchange also proposes a non-substantive change to paragraph (b) of Rule 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility) to correct a cross reference to Market Maker quoting obligations as set forth in Rule 6.37AP–O(b) and (c). Current Rule 6.65A(b) erroneously cross-references Rule 6.37B–O(b) and (c).

In connection with proposed Rule 6.37AP–O, the Exchange proposes to add the following preamble to Rule 6.37A–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.37A–O would not be applicable to trading on Pillar.

Proposed Rule 6.40P–O: Pre-Trade and Activity-Based Risk Controls

For the OX system, current Rule 6.40–O sets forth the activity-based Risk Limitation Mechanisms for orders and quotes, which are designed to help OTP Holders and OTP Firms effectively manage risk during periods of increased and significant trading activity. With the transition to Pillar, the Exchange proposes to incorporate new risk control functionality that is based on both existing activity-based risk controls for options and pre-trade risk controls that are available on the Exchange's cash equity platform. Proposed Rule 6.40P–O would describe the activity-based controls with updated functionality under Pillar and would also describe new optional pre-trade risk controls that are based on pre-trade risk controls available on the Exchange's cash equity platform, as described in Rule 7.19–E, with proposed differences to reference quotes and proposed new Pillar functionality.

Proposed Rule 6.40P–O(a) would set forth the following definitions that would be used for purposes of the Rule:

• The term ''Entering Firm'' would mean an OTP Holder or OTP Firm (including those acting as Market Makers) (proposed Rule 6.40P–O(a)(1)). This proposed definition is based in part on the definition of ''Entering Firm'' in Rule 7.19–E(a)(1) and the Exchange believes that the addition of this term would add clarity to the proposed rule.

• The term ''Pre-Trade Risk Controls'' would refer to two optional limits that an Entering Firm may utilize with respect to its trading activity on the Exchange (proposed Rule 6.40P–O(a)(2)). These controls would be the ''Single Order Maximum Notional Value Risk Limit'' and the ''Single Order Maximum Quantity Risk Limit.'' The proposed Pre-Trade Controls are based on the substantially identical risk controls available on the Exchange's cash equity market, as described in Rules 7.19–E(a)(3) and (4), respectively, but differ in that the proposed rule would also apply to quotes and specifies the treatment of orders designated GTC.

○ The term ''Single Order Maximum Notional Value Risk Limit'' would refer to a pre-established maximum dollar amount for a single order or quote to be applied one time (proposed Rule 6.40P–O(a)(2)(A)). This definition would also provide that orders designated GTC would be subject to this pre-trade risk control only once.

○ The term ''Single Order Maximum Quantity Risk Limit'' would refer to a pre-established maximum number of contracts that may be included in a single order or quote before it can be traded (proposed Rule 6.40P–O(a)(2)(B)). This definition would also provide that orders designated GTC would be subject to this pre-trade risk control only once.

• The term ''Activity-Based Risk Controls'' would refer to three activity-based risk limits that an Entering Firm may apply to its orders and quotes in an options class based on specified thresholds measured over the course of an Interval (to be defined below) (proposed Rule 6.40P–O(a)(3)). The proposed Activity-Based Risk Controls are based on the substantially identical risk controls set forth in current Rule 6.40–O(b)–(d), except that on Pillar, a Market Maker's orders and quotes would be aggregated and applied towards each risk limit (as opposed to current functionality, where a Market Maker's orders and quotes are counted separately).

○ The term ''Transaction-Based Risk Limit'' would refer to a pre-established limit on the number of an Entering Firm's orders and quotes executed in a specified class of options per Interval (proposed Rule 6.40P–O(a)(3)(A)). This risk control is based on the substantially identical risk control set forth in current Rule 6.40–O(b), except as noted above.

○ The term ''Volume-Based Risk Limit'' would refer to a pre-established limit on the number of contracts of an Entering Firm's orders and quotes that could be executed in a specified class of options per Interval (proposed Rule 6.40P–O(a)(3)(B)). This risk control is based on the substantially identical risk control set forth in current Rule 6.40–O(c), except as noted above.

○ The term ''Percentage-Based Risk Limit'' would refer to a pre-established limit on the percentage of contracts executed in a specified class of options as measured against the full size of such Entering Firm's orders and quotes executed per Interval (proposed Rule 6.40P–O(a)(3)(C)). The proposed definition would also provide that to determine whether an Entering Firm has breached the specified percentage limit, the Exchange would calculate the percent of each order or quote in a

specified class of option that is executed during an Interval (each, a ''percentage''), and sum up those percentages. As further proposed this definition would state that this risk limit would be breached if the sum of the percentages exceeds the pre-established limit. This risk control is based on the substantially identical risk control set forth in current Rule 6.40–O(d), except as noted above.

• The term ''Global Risk Control'' would refer to a pre-established limit on the number of times an Entering Firm may breach its Activity-Based Risk Controls per Interval (proposed Rule 6.40P–O(a)(4)). This proposed definition is based on the substantially identical functionality set forth in current Rule 6.40–O(f).

• The term ''Interval'' would refer to the configurable time period during which the Exchange would determine if an Activity-Based Risk Control or the Global Risk Control has been breached (proposed Rule 6.40P–O(a)(5)). This proposed definition is consistent with current Rule 6.40–O, which contains references throughout to a ''time period'' during which the Exchange will determine whether a breach has occurred. The Exchange believes this proposed definition would add clarity and transparency to Exchange rules.

Proposed Rule 6.40P–O(b) would set forth how the Pre-Trade, Activity-Based and Global Risk Controls could be set or adjusted. Proposed Rule 6.40P–O(b)(1) would provide that these risk controls may be set before the beginning of a trading day and may be adjusted during the trading day. Proposed Rule 6.40P–O(b)(2) would provide that Entering Firms may set these risk controls at the MPID level or at one or more sub-IDs associated with that MPID, or both. Proposed Rule 6.40P–O(b) is based on Rule 7.19–E(b)(3)(A)–(B) but differs in that the proposed rule includes Activity-Based and Global Risk Controls in addition to Pre-Trade Risk Controls.

Proposed Rule 6.40P–O(c) would set forth the Automated Breach Actions that the Exchange would take if a designated risk limit is breached. Proposed Rule 6.40P–O(c)(1)(A)(i)–(ii) would set forth the automated breach actions for the Pre-Trade Risk Controls.

• Proposed Rule 6.40P–O(c)(1)(A)(i) would provide that a Limit Order or quote that breaches the designated limit of either a Single Order Maximum Notional Value Risk Limit or Single Order Maximum Quantity Risk Limit would be rejected.

• Proposed Rule 6.40P–O(c)(1)(A)(ii) would provide that a Market Order that breaches the designated limit of a Single Order Maximum Quantity Risk Limit would be rejected. The proposed rule would also provide that a Market Order that breaches the designated limit of a Single Order Notional Value Risk Limit would be rejected if the order arrived during continuous trading or canceled if the order was received during a pre-open state and the quantity remaining to trade after an Auction concludes breaches the designated limit.

Proposed Rule 6.40P–O(c)(1)(A)(i)–(ii) is based on Rule 7.19–E(c)(2) but differs in that it specifies the treatment of Limit Orders and Market Orders (the latter having different treatment based on when such orders arrive at the Exchange) and expands application of the check to include quotes.

Proposed Rule 6.40P–O(c)(2) would set forth the automated breach actions for the Activity-Based Risk Controls.

• Proposed Rule 6.40P–O(c)(2)(A) would first specify that an Entering Firm acting as a Market Maker would be required to apply one of the Activity-Based Risk Controls to all of its orders and quotes; whereas an Entering Firm that is not acting as a Market Maker would have the option, but would not be required, to apply one of the Activity-Based Risk Controls to its orders. The requirement that Market Makers utilize Activity-Based Risk Controls for all quotes mirrors the requirements set forth in Rule 6.40–O, Commentary .04(a); however, the proposed rule differs in that it likewise requires Market Makers to apply one of the Activity-Based Risk Controls to all of its orders. The proposed optionality of the Activity-Based Risk controls for orders sent by Entering Firms not acting as Marker Maker mirrors current Rule 6.40–O, Commentary .04(b)).

• Proposed Rule 6.40P–O(c)(2)(B) would provide that to determine when an Activity-Based Risk Control has been breached, the Exchange would maintain Trade Counters that would be incremented every time an order or quote trades, including any leg of a Complex Order, and would aggregate the number of contracts traded during each such execution. As further proposed, an Entering Firm may opt to exclude any orders designated IOC or FOK from being considered by a Trade Counter. This is consistent with existing functionality set forth in Rule 6.40–O(a) and Commentary .07, except, as noted above, there would not be separate Trade Counters for a Market Maker's quotes and orders. Instead, a Market Maker's quotes and orders in a given option class would be aggregated (*i.e.,* counted together).

• Proposed Rule 6.40P–O(c)(2)(C) would provide that each Entering Firm must select one of three Automated Breach Actions for the Exchange to take should the Entering Firm breach an Activity-Based Risk Control.

○ ''Notification Only.'' As set forth in proposed Rule 6.40P–O(c)(2)(C)(i), if this option is selected, the Exchange would continue to accept new order and quote messages and related instructions and would not cancel any unexecuted orders or quotes in the Consolidated Book. With the ''Notification Only'' action, the Exchange would provide such notifications, but would not take any other automated actions with respect to new or unexecuted orders. This proposed functionality is not currently available in the event of a breach of current Rule 6.40–O, but is substantially identical to the Notification Only option set forth in Rule 7.19–E(c)(3)(A)(i) for breach of the Gross Credit Risk Limit on the Exchange's cash equity platform. The Exchange believes this proposed option would provide Entering Firms more control over how Activity-Based Risk Controls are implemented and would add consistency to the risk controls already offered under Pillar on the Exchange's cash equity platform.

○ ''Block Only.'' As set forth in proposed Rule 6.40P–O(c)(2)(C)(ii), if this option is selected, the Exchange would reject new order and quote messages and related instructions, provided that the Exchange would continue to process instructions from the Entering Firm to cancel one or more orders or quotes (including Auction-Only Orders) in full. The proposed rule would also provide that the Exchange would follow any instructions specified in paragraph (e) of the proposed Rule (and described below). This proposed functionality is not currently available under current Rule 6.40–O, but is substantially identical to the Block Only option set forth in Rule 7.19–E(c)(3)(A)(ii) for breach of the Gross Credit Risk Limit on the Exchange's cash equity platform. The Exchange believes this proposed option would provide Entering Firms more control over how Activity-Based Risk Controls are implemented and would add consistency to the risk controls already offered under Pillar on the Exchange's cash equity platform.

○ ''Cancel and Block.'' As set forth in proposed Rule 6.40P–O(c)(2)(C)(iii), if this option is selected, in addition to the Block actions described above, the Exchange would also cancel all unexecuted orders and quotes in the Consolidated Book other than Auction-Only Orders and orders designated GTC. This proposed Cancel and Block functionality is substantially similar to the automated breach action taken by

the Exchange per current Rule 6.40–O(e) and Commentaries .01 and .02 thereto, except that under the current rules, this is default (not optional) functionality. Additionally, this proposed rule is substantially identical to the Cancel and Block option set forth in Rule 7.19–E(c)(3)(A)(iii) for breach of the Gross Credit Risk Limit on the Exchange's cash equity platform. The Exchange believes this proposed option would provide Entering Firms more control over how Activity-Based Risk Controls are implemented and would add consistency to the risk controls already offered under Pillar on the Exchange's cash equity platform.

• Finally, proposed Rule 6.40P–O(c)(2)(D) would provide that if an Entering Firm breaches an Activity-Based Risk Control, the Automated Breach Action selected would be applied to its orders and quotes in the affected class of options. This proposed action is consistent with current Rule 6.40–O(e) and Commentaries .01 and .02 thereto which provide that, upon a breach, the Exchange will cancel existing and suspend new orders and quotes trading in the affected class.

Proposed Rule 6.40P–O(c)(2)(E) would provide that the Exchange would specify by Trader Update any applicable minimum, maximum and/or default settings for the Activity-Based Risk Controls, subject to the following:

• For the Transaction-Based Risk Limit, the minimum setting would not be less than one and the maximum setting would not be more than 2,000 (proposed Rule 6.40P–O(c)(2)(E)(i)).

• For the Volume-Based Risk Limit, the minimum setting would not be less than one and the maximum setting would not be more than 500,000 (proposed Rule 6.40P–O(c)(2)(E)(ii)).

• For the Percentage-Based Risk Limit, the minimum setting would not be less than 50 and the maximum setting would not be more than 200,000 (proposed Rule 6.40P–O(c)(2)(E)(iii)).

These proposed settings are identical to the Exchange-determined settings provided under current Rule 6.40–O, Commentary .03.

Proposed Rule 6.40P–O(c)(2)(F) would provide that the Exchange would specify by Trader Update the Interval for the Activity-Based Risk Controls, subject to the following:

• The Interval would not be less than 100 milliseconds and would not be greater than 300,000 milliseconds, inclusive of the duration of any trading halt occurring within that time (proposed Rule 6.40P–O(c)(2)(F)(i)).

• For transactions occurring in the Core Open Auction, per Rule 6.64P–O, the applicable time period would be the lesser of (i) the time between the Core Open Auction of a series and the initial transaction or (ii) the Interval (proposed Rule 6.40P–O(c)(2)(F)(ii)).

These proposed settings are identical to the Exchange-specified time periods provided under current Rule 6.40–O, Commentary .03, except that the Exchange has included a maximum allowable time period for the Interval, which adds clarity to the rule.

Proposed Rule 6.40P–O(c)(3) would set forth the automated breach actions for the Global Risk Controls set by an Entering Firm.

• Proposed Rule 6.40P–O(c)(3)(A) would provide that if the Global Risk Control limit is breached, the Exchange would Cancel and Block, per proposed Rule 6.40P(c)(2)(C)(iii).

• Proposed Rule 6.40P–O(c)(3)(B) would provide that if an Entering Firm breaches the Global Risk Control, the Automated Breach Action would be applied to all orders and quotes of the Entering Firm in all classes of options regardless of which class(es) of options caused the underlying breach of Activity-Based Risk Controls. This proposed functionality is consistent with the automated breach action taken in the event of a breach of current Rule 6.40–O(f), per current Rule 6.40–O, Commentaries .01 and .02.

• Proposed Rule 6.40P–O(c)(3)(C) would provide that the Exchange would specify by Trader Update any applicable minimum, maximum and/or default settings for the Global Risk Controls, provided that the minimum setting would not be less than 25 and the maximum setting would not be more than 100. These proposed settings are based on the Exchange-determined setting provided under current rule 6.40–O, Commentary .03, except that the current rule allows for a minimum setting of one (1) whereas the proposed rule is increasing that minimum to twenty-five (25), which the Exchange believes is a more appropriate minimum.

• Proposed Rule 6.40P–O(c)(3)(D) would provide that the Exchange would specify by Trader Update the Interval for the Global Risk Controls, subject to the following:

○ The Interval would not be less than 100 milliseconds and would not be greater than 300,000 milliseconds, inclusive of the duration of any trading halt occurring within that time, per proposed Rule 6.40P–O(c)(3)(D)(i).

○ For transactions occurring in the Core Open Auction, per Rule 6.64P–O, the applicable time period is the lesser of (i) the time between the Core Open Auction of a series and the initial transaction or (ii) the Interval, per proposed Rule 6.40P–O(c)(3)(D)(ii).

Proposed Rule 6.40P–O(d) describes how an Entering Firm's ability to enter orders, quotes, and related instructions would be reinstated after a ''Block Only'' or ''Cancel and Block'' Automated Breach Action has been triggered. In such case, proposed Rule 6.40P–O(d) provides that the Exchange would not reinstate the Entering Firm's ability to enter orders and quotes and related instructions on the Exchange (other than instructions to cancel one or more orders or quotes (including Auction-Only Orders and orders designated GTC) in full) without the consent of the Entering Firm, which may be provided via automated contact if it was a breach of an Activity-Based Risk Control. As further proposed, an Entering Firm that breaches the Global Risk Control would not be reinstated unless the Entering Firm provides consent via non-automated contact with the Exchange. This proposed functionality is consistent with current Rule 6.40–O, Commentary .02 regarding the need for an Entering Firm to make automated or non-automated contact with the Exchange, as applicable, prior to being reinstated. Proposed Rule 6.40P–O(d) is also consistent with the more granular level of risk control under Pillar functionality available for cash equity trading per Rule 7.19–E(d).

Proposed Rule 6.40P–O(e) would set forth new ''kill switch'' functionality, which would allow an Entering Firm to direct the Exchange to take certain bulk cancel or block actions with respect to orders and quotes. In contrast to the Automated Breach Actions described above, which the Exchange would take automatically after the breach of a risk limit, the Exchange would not take any of the Kill Switch Actions without express direction from an Entering Firm.

Proposed Rule 6.40P–O(e) would specify that an Entering Firm could direct the Exchange to take one or more of the following actions with respect to orders and quotes at either an MPID, or if designated, sub-ID Level: (1) Cancel all Auction-Only Orders; (2) Cancel all orders designated GTC; (3) Cancel all unexecuted orders and quotes in the Consolidated Book other than Auction-Only Orders and orders designated GTC; or (4) Block the entry of any new order and quote messages and related instructions, provided that the Exchange would continue to accept instructions from Entering Firms to cancel one or more orders or quotes (including Auction-Only Orders and orders designated GTC) in full, and later, reverse that block. The proposed post-trade Kill Switch Actions are not

currently available per Rule 6.40–O and are substantially identical to the Kill Switch Action available on the Exchange's cash equity platform pursuant to Rule 7.19–E(e), with a difference to address the handling of orders designated GTC, which are not available on the cash equity platform. The Exchange believes that offering this functionality for options trading under Pillar would give Entering Firms more flexibility in setting risk controls for options trading and add consistency with the Exchange's risk control functionality available for cash equity trading.

Proposed Commentary .01 to Rule 6.40P–O would provide that the Pre-Trade, Activity-Based, and Global Risk Controls described in the proposed Rule 6.40P–O are meant to supplement, and not replace, the OTP Holder's or OTP Firm's own internal systems, monitoring, and procedures related to risk management and are not designed for compliance with Rule 15c3–5 under the Exchange Act.[45] Responsibility for compliance with all Exchange and SEC rules remains with the OTP Holder or OTP Firm. This proposed language is not included in existing Rule 6.40–O, and is based on Commentary .01 to Rule 7.19–E. The proposed rule makes clear that use of the proposed controls alone does not constitute compliance with Exchange rules or the Exchange Act.

In connection with proposed Rule 6.40P–O, the Exchange proposes to add the following preamble to Rule 6.40–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.40–O would not be applicable to trading on Pillar.

Proposed Rule 6.41P–O: Price Reasonability Checks—Orders and Quotes

The Exchange proposes to describe its Price Reasonability Checks for orders and quotes in proposed Rule 6.41P–O.[46] For the OX system, the concept of ''Price Reasonability Checks'' for Limit Orders are described in Rule 6.60–O(c) and the concept of price protection filters for quotes are described in Rule 6.61–O. The proposed ''Price Reasonability Checks'' on Pillar would be applicable to both orders and quotes and would work similarly to how the current price checks for Limit Orders function on the OX system, with updates to functionality consistent with Pillar. The Exchange proposes to locate the rule text for the proposed Price Reasonability Checks in Rule 6.41P–O to immediately follow Rule 6.40P–O regarding the Pre-Trade and Activity-Based Controls, as this placement would group the risk controls together and make Exchange rules easier to navigate.

Proposed Rule 6.41P–O(a)(1)–(3) would set forth the circumstances under which the proposed Price Reasonability Checks would apply. Proposed Rule 6.41P–O(a) would provide that the Exchange would apply the Price Reasonability Checks, as defined in proposed paragraphs (b) and (c), to all Limit Orders and quotes during continuous trading on each trading day, subject to the following:

- Proposed Rule 6.41P–O(a)(1) would provide that a Limit Order or quote received during a pre-open state would be subject to the proposed Price Reasonability Checks after an Auction concludes; that a Limit Order or quote that was resting on the Consolidated Book before a trading halt would be subject to the proposed Price Reasonability Checks again after the Trading Halt Auction; and that a put option message to buy would be subject to the Arbitrage Check regardless of when it arrives. This proposed rule is based in part on current Rule 6.60–O(a), which provides that the Price Reasonability Checks (for orders) are applied when a series opens or reopens for trading. Proposed Rule 6.41P–O(a)(1) adds additional detail and granularity regarding when the proposed Price Reasonability Checks would be applied under Pillar.
- Proposed Rule 6.41P–O(a)(2) would provide that if the calculation of the Price Reasonability Check is not consistent with the MPV for the series, it would be rounded down to the nearest price within the applicable MPV, which text adds new details regarding Pillar rounding functionality.
- Proposed Rule 6.41P–O(a)(3) would provide that the proposed Price Reasonability Checks would not apply to (i) any options series for which the underlying security has a non-standard cash or stock deliverable as part of a corporate action; (ii) any options series for which the underlying security is identified as over-the-counter (''OTC''); (iii) any option series on an index; and (iv) any option series for which the Exchange determines it is necessary to exclude underlying securities in the interests of maintaining a fair and orderly market, which the Exchange would announce by Trader Update. Proposed Rule 6.41P–O(a)(3) is based on current Commentary .01 to Rule 6.60–O (orders) and 6.61–O (quotes), with a non-substantive difference that the proposed rule no longer references Binary Return Derivatives (''ByRDs'') because ByRDs are no longer traded on the Exchange.

Proposed Rule 6.41P–O(b) would set forth the ''Arbitrage Checks'' for buy orders or quotes, which subset of Price Reasonability Checks are based on the principle that an option order is in error and should be rejected (or canceled) when the same result can be achieved on the market for the underlying equity security at a lesser cost.

- Proposed Rule 6.41P–O(b)(1) relates to ''puts'' and would provide that order or quote messages to buy for put options would be rejected if the price of the order or quote is equal to or greater than the strike price of the option, which is substantively identical to current Rule 6.60–O(c)(1)(A) for orders, with a proposed difference that proposed ''Arbitrage Check'' would also apply to quotes.
- Proposed Rule 6.41P–O(b)(2) relates to ''calls'' and would provide that order or quote messages to buy for call options would be rejected or canceled (if resting) if the price of the order or quote is equal to or greater than the last sale price of the underlying security on the Primary Market, plus a specified dollar amount to be determined by the Exchange and announced by Trader Update. This proposed rule is substantially similar to current Rule 6.60–O(c)(1)(B) for orders, with two differences. First, the proposed ''Arbitrage Checks'' would also apply to quotes. Second, because the Exchange is monitoring last sales from the Primary Market, the Exchange proposes that the Exchange-specified dollar amount for the Checks would be based on the last sale on the Primary Market rather than on the Consolidated Last Sale.

Proposed Rule 6.41P–O(c) would set forth the ''Intrinsic Value Checks'' for orders or quotes to sell, which are designed to protect sellers of calls and puts from presumptively erroneous executions based on the ''Intrinsic Value'' of an option.

- Proposed Rule 6.41P–O(c)(1)–(2) would set forth how the Intrinsic Value of an option would be determined. Proposed Rule 6.41P–O(c)(1) would provide that the Intrinsic Value for a put option is equal to the strike price minus the last sale price of the underlying security on the Primary Market. Proposed Rule 6.41P–O(c)(2) would provide that the Intrinsic Value for a call option is equal to the last sale price of the underlying security on the Primary Market minus the strike price. Proposed Rule 6.41P–O(c)(1)–(2) is based on how the intrinsic value is

[45] 17 CFR 240.15c3–5.

[46] Current Rule 6.41–O is held as Reserved. The Exchange proposes to renumber the proposed rule with the ''P'' modifier and remove reference to ''Reserved.''

calculated in current Rule 6.60–O(c)(2) for orders, with two differences. First, the proposed ''Intrinsic Value Checks'' would also apply to quotes. Second, the Intrinsic Value of an option would be based on the last sale on the Primary Market rather than on the Consolidated Last Sale.

• Proposed Rule 6.41P–O(c)(3) would provide that ISOs to sell would not be subject to the Intrinsic Value Check, which carve out is substantively identical to current Rule 6.60–O(c)(2).

• Proposed Rule 6.41P–O(c)(4) would describe the application of the Intrinsic Value Checks to puts and calls to sell.

○ Proposed Rule 6.41P–O(c)(4)(A) would provide that orders or quotes to sell for both puts and calls would be rejected or canceled (if resting) if the price of the order or quote is equal to or lower than its Intrinsic Value, minus a threshold percentage to be determined by the Exchange and announced by Trader Update.

○ Proposed Rule 6.41P–O(c)(4)(B) would provide that the Exchange-determined threshold percentage (per paragraph (c)(4)(A)) would be based on the NBB, provided that, immediately following an Auction, it would be based on the Auction Price, or, if none, the lower Auction Collar price, or, if none, the NBB. This proposed threshold percentage is similar to how the Reference Price would be determined for Trading Collars, as described above pursuant to proposed Rule 6.62P–O(a)(3). As further proposed, Rule 6.41P–O(c)(4)(B) would provide that for purposes of determining the Intrinsic Value, the Exchange would not use an adjusted NBBO. The Exchange further proposes that the Intrinsic Value Check for sell orders and quotes would not be applied if the Intrinsic Value cannot be calculated.

Proposed Rule 6.41P–O(c)(4)(A)–(B) is substantially similar to current Rule 6.60–O(a)(2)(A), which sets forth the Intrinsic Value for orders, except that the proposed rule would also apply to quotes and provides additional detail regarding how the threshold percentage for determining the Intrinsic Value would be applied depending on when such sell order or quote arrives and the potential reference price(s) available to calculate this Price Reasonability Check.

Proposed Rule 6.41P–O(d) would provide the Automated Breach Action to be applied when a Market Maker's order or quote fails one of the Price Reasonability Checks. As proposed, if a Market Maker's order or quote message is rejected or cancelled (if resting) pursuant to proposed paragraph (b) (Arbitrage Checks) or (c) (Intrinsic Value Checks) of proposed Rule 6.41P–O, the Exchange would Cancel and Block orders and quotes in the affected class of options as described in Rule 6.40P–O(c)(2)(C)(iii) (as described above in section ''Proposed Rule 6.40P–O'').

Proposed Rule 6.41P–O(d)(1) would provide that a breach of proposed Rule 6.41P–O(d) would count towards a Market Maker's Global Risk Control limit per Rule 6.40P–O(a)(4) (as described above in section ''Proposed Rule 6.40P–O'').

Proposed Rule 6.41P–O(d)(2) concerns how a Market Maker would be reinstated following an automated breach action. As proposed, the Exchange would not reinstate the Market Maker's ability to enter orders and quotes and related instructions on the Exchange in that class of options (other than instructions to cancel one or more orders/quotes (including Auction-Only Orders and orders designated GTC) in full) without the consent of the Market Maker, which may be provided via automated contact.

Rule 6.41P–O(d) is substantially similar to current Rule 6.61–O(b), except that the proposed rule applies to both the orders and quotes of a Market Maker (not just quotes) and provides the additional functionality that a breach of the Price Reasonability Checks would count towards a Market Maker's Global Risk Control limit under proposed Rule 6.40P–O(c)(3), which functionality would be new under Pillar.

In connection with proposed Rule 6.41P–O, the Exchange proposes to add the following preamble to Rules 6.60–O and 6.61–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rules 6.60–O and 6.61–O would not be applicable to trading on Pillar.

Proposed Rule 6.64P–O: Auction Process

Current Rule 6.64–O, OX Opening Process, sets forth the opening process currently used on the Exchange's OX system for opening trading in a series each day and reopening trading in a series following a trading halt. The Exchange proposes that new Rule 6.64P–O would set forth the auction process for both opening and reopening trading in a series on the Exchange. The Exchange proposes to specify that Rule 6.64–O would not be applicable to trading on Pillar.

With the transition to Pillar, the Exchange proposes new functionality regarding the auction process on the Exchange. In addition, certain functionality available on the Exchange's cash equity platform will now be available for options trading. Accordingly, the Exchange proposes that proposed Rule 6.64P–O would use Pillar terminology relating to auctions that is based on Pillar terminology set forth in Rule 7.35–E for cash equity trading.

Definitions. Proposed Rule 6.64P–O(a) would provide that the Rule would be applicable to all series that trade on the Exchange other than Flex Options.[47] Proposed Rule 6.64P–O(a) would further set forth the definitions that would be used for purposes of Rule 6–O Options Trading that would be applicable to trading on Pillar.

• Proposed Rule 6.64P–O(a)(1) would define the term ''Auction'' to mean the opening or reopening of a series for trading either on a trade or a quote. This proposed definition is based in part on current Rule 6.64–O(a), which defines the term ''Trading Auction'' to be a process by which trading is initiated in a specified options class that may be employed at the opening of the Exchange each business day or to re-open trading after a trading halt. On Pillar, the Exchange proposes that the term ''Auction'' would refer to the point in the process where the Exchange determines that a series can be opened or reopened either on a trade or a quote.

Proposed Rule 6.64P–O(a)(1)(A) would provide that a ''Core Open Auction'' means the Auction that opens trading after the beginning of Core Trading Hours and proposed Rule 6.64P–O(a)(1)(B) would provide that a ''Trading Halt Auction'' means the Auction that reopens trading following a trading halt. These are Pillar terms currently used in Rule 7.35–E for the same purposes.

• Proposed Rule 6.64P–O(a)(2) would define the term ''Auction Collar'' to mean the price collar thresholds for the Indicative Match Price for an Auction. As further proposed, the upper Auction Collar would be the offer of the Legal Width Quote (defined below) and the lower Auction Collar would be the bid of the Legal Width Quote, provided that if the bid of the Legal Width Quote is zero, the lower Auction Collar would be one MPV above zero for the series. The proposed rule would further provide that if there is no Legal Width Quote, the Auction Collars would be published

[47] With the transition to Pillar, the Exchange is not making any changes to how Flex Options trade. Rule 5.31–O provides that Flex Options transactions may be effected during normal Exchange options trading hours on any business day and there will be no trading rotations in Flex Options. Rule 5.33–O sets forth the procedures for trading Flex Options. The opening process for Electronic Complex Orders is set forth in Rule 6.91–O.

in the Auction Imbalance Information (defined below) as zero.

The proposed terminology of ''Auction Collars'' would be new for options trading and is based on the same term used in Rule 7.35–E for trading cash equity securities. However, the concept would not be novel because currently, the Exchange will not open a series if the bid-ask differential is not within the bid-ask differential guidelines established under Rule 6.37–O(b)(4).[48] Auction Collars would function similarly to prevent an Auction that results in a trade from being priced outside the Legal Width Quote.

• Proposed Rule 6.64P–O(a)(3) would define the term ''Auction Imbalance Information'' to mean the information that the Exchange disseminates about an Auction via its proprietary data feeds and includes the Auction Collars, Auction Indicator, Book Clearing Price, Far Clearing Price, Indicative Match Price, Matched Volume, Market Imbalance, and Total Imbalance. With Pillar, the Exchange proposes to disseminate Auction Imbalance Information for its options market in the same manner that such information is disseminated for its cash equity market. Accordingly, this proposed definition is based on Rule 7.35–E, with differences to reflect the content that would be included in Auction Imbalance Information for options trading. In addition, the Exchange proposes that the Auction Imbalance Information would reflect the orders and quotes eligible to participate in an Auction and that contribute to price discovery. Accordingly, proposed Rule 6.64P–O(a)(3) would further provide that Auction Imbalance Information would be based on all orders and quotes (including the non-displayed quantity of Reserve Orders) eligible to participate in an Auction, excluding IO Orders.[49]

Proposed Rule 6.64P–O(a)(3)(A) would define the term ''Auction Indicator'' to mean the indicator that provides a status update of whether an Auction cannot be conducted because either (i) there is no Legal Width Quote, or (ii) a Market Maker quote has not been received during the Opening MMQ Time Parameter (defined below). The Exchange currently disseminates an Auction Indicator on its cash equity market and proposes similar functionality for options trading on the Exchange.[50]

Proposed Rule 6.64P–O(a)(3)(B) would define the term ''Book Clearing Price'' to mean the price at which all contracts could be traded in an Auction if not subject to the Auction Collar and that the Book Clearing Price would be zero if a sell (buy) Imbalance cannot be filled by any buy (sell) interest. The Exchange proposes that the manner that the Book Clearing Price would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition is based in part on the definition of ''Book Clearing Price'' set forth in Rule 7.35–E(a)(11), with differences to reflect options trading terminology.

Proposed Rule 6.64P–O(a)(3)(C) would define the term ''Far Clearing Price'' to mean the price at which all Auction-Only Orders could be traded in an Auction within the Auction Collar. The Exchange proposes that the manner that the Far Clearing Price would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition is based on the definition of ''Far Clearing Price'' set forth in Rule 7.35–E(a)(12), without any differences.

Proposed Rule 6.64P–O(a)(3)(D) would define the term ''Imbalance'' to mean the number of buy (sell) contracts that cannot be matched with sell (buy) contracts at the Indicative Match Price at any given time. The Exchange proposes that the manner that the Imbalance would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition is based in part on the definition of ''Imbalance'' set forth in Rule 7.35–E(a)(7), with differences to reflect options trading terminology.

Proposed Rule 6.64P–O(a)(3)(D)(i) would define the term ''Total Imbalance'' to mean the Imbalance of all buy (sell) contracts at the Indicative Match Price for all orders and quotes eligible to trade in an Auction. The Exchange proposes that the manner that the Total Imbalance would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition is based in part on the definition of ''Total Imbalance'' set forth in Rule 7.35–E(a)(7)(A), with differences to reflect options trading terminology.

Proposed Rule 6.64P–O(a)(3)(D)(ii) would define the term ''Market Imbalance'' to mean the Imbalance of any remaining buy (sell) Market Orders and MOO Orders that are not matched for trading in the Auction. The Exchange proposes that the manner that the Market Imbalance would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition is based in part on the definition of ''Market Imbalance'' set forth in Rule 7.35–E(a)(7)(B), with differences to reflect options trading terminology.

• Proposed Rule 6.64P–O(a)(4) would define the term ''Auction Process'' to mean the process that begins when the Exchange receives an Auction Trigger (defined below) for a series and ends when the Auction is conducted. This would be a new term and is designed to address all steps in the process that culminates in an Auction, as described in proposed Rule 6.64P–O(d).

• Proposed Rule 6.64P–O(a)(5) would define the term ''Auction Processing Period'' to mean the period during which the Auction is being processed. The Exchange proposes that this term would have the same meaning as the same term on its cash equity market. Accordingly, this proposed definition is based in part on the definition of ''Auction Processing Period'' set forth in Rule 7.35–E(a)(2), without any differences.

• Proposed Rule 6.64P–O(a)(6) would define the term ''Auction Trigger'' to mean the information disseminated by the Primary Market in the underlying security that triggers the Auction Process for a series to begin. For a Core Open Auction, the Auction Trigger would be when the Primary Market first disseminates at or after 9:30 a.m. Eastern Time both a two-sided quote and a trade of any size that is at or within the quote. For a Trading Halt Auction, the Auction Trigger would be when the Primary Market disseminates at the end of a trading halt or pause a resume message, a two-sided quote, and a trade of any size that is at or within the quote. This proposed functionality is not new and is based on how the Exchange currently opens or reopens a series for trading, as set forth in the last sentence of current Rule 6.64–O(b). The Exchange proposes to use Pillar terminology, including to specify that an odd-lot transaction on the Primary Market could be used as an Auction Trigger, which would be new on Pillar.

• Proposed Rule 6.64P–O(a)(7) would define the term ''Indicative Match Price'' to mean the price at which the maximum number of contracts can be traded in an Auction, including the non-displayed quantity of Reserve Orders and excluding IO Orders, subject to the

[48] *See* Rule 6.64–O(b)(D) and (E).

[49] This is consistent with the order information included in Auction Imbalance Information for cash equity trading. *See* Rule 7.35–E(a)(7) and 7.35–E(a)(8). The Exchange proposes to exclude IO Orders because they are conditional offsetting orders that would not contribute to price discovery in the Auction Process.

[50] *See* Rule 7.35–E(a)(13).

Auction Collars. This proposed definition is based on Rule 7.35–E(a)(8) with non-substantive differences to reflect options trading terminology (*i.e.,* contracts instead of shares). Proposed Rule 6.64P–O(a)(7) would further provide that if there is no Legal Width Quote, the Indicative Match Price included in the Auction Imbalance Information would be calculated without Auction Collars. This would be a new feature applicable only to options trading and an Indicative Match Price without Auction Collars would be accompanied with an Auction Indicator that the Auction cannot be conducted because there is no Legal Width Quote.

Proposed Rule 6.64P–O(a)(7)(A) would provide that if there is more than one price level at which the maximum number of contracts can be traded within the Auction Collars, the Indicative Match Price would be the price closest to the midpoint of the Legal Width Quote, rounded to the nearest MPV for the series, provided that the Indicative Match Price will not be lower (higher) than the highest (lowest) price of a Limit Order to buy (sell) ranked Priority 2—Display Orders that is eligible to participate in the Auction. This proposed rule text is based on Rule 7.31–E(a)(8)(A) with a substantive difference only to reflect that in such circumstances, the Indicative Match Price would be the price closest to the midpoint of the Legal Width Quote rather than the price closest to an auction reference price.

Proposed Rule 6.64P–O(a)(7)(B) would provide that an Indicative Match Price that is higher (lower) than the upper (lower) Auction Collar would be adjusted to the upper (lower) Auction Collar and orders eligible to participate in the Auction would trade at the collared Indicative Match Price. Proposed Rule 6.64P–O(a)(7)(B)(i) would provide that Limit Orders to buy (sell) with a limit price above (below) the upper (lower) Auction Collar would be included in the Auction Imbalance Information at the collared Indicative Match Price and would be eligible to trade at the Indicative Match Price. Proposed Rule 6.64P–O(a)(7)(B)(ii) would provide that Limit Orders and quotes to buy (sell) with a limit price below (above) the lower (upper) Auction Collar would not be included in the Auction Imbalance Information and would not participate in an Auction. The Exchange proposes that the manner that orders and quotes priced outside of the Auction Collar would be included in the Indicative Match Price would be the same as how it is determined for cash equity trading. Accordingly, this proposed rule text is based on Rules 7.31–E(a)(10)(A), (B), and (C) with a difference only to reflect when the proposed rule would be applicable to quotes.

Proposed Rule 6.64P–O(a)(7)(C) would provide that if the Matched Volume (defined below) for an Auction consists of only buy and sell Market Orders, the Indicative Match Price would be the midpoint of the Legal Width Quote, rounded to the MPV for the series, or, if the Legal Width Quote is locked, the locked price. This proposed rule text is based in part on Rule 7.31–E(a)(8)(C), with differences to reflect that options trading is based on a Legal Width Quote.

Proposed Rule 6.64P–O(a)(7)(D) would provide that if there is no Matched Volume, including if there are Market Orders on only one side of the Market, the Indicative Match Price and Total Imbalance for the Auction Imbalance Information would be zero. This proposed rule text is based on Rule 7.31–E(a)(8)(D) and (E) with differences to reflect that on options, the Indicative Match Price would be zero in both circumstances.

• Proposed Rule 6.64P–O(a)(8) would define the term ''Legal Width Quote'' to mean the highest bid and lowest offer among all Market Maker quotes and the Away Market NBBO (together, ''Calculated NBBO'') during the Auction Process. The proposed rule would further provide that the Calculated NBBO can be a Legal Width Quote if it: (A) It is locked, but not crossed; (B) does not contain a zero offer; and (C) has a spread between the Calculated NBBO for each option contract that does not exceed the following differentials, which can be widened as provided for in Rule 6.37–O(c): (i) No more than .25 where the bid not does exceed $2; (ii) no more than .40 where the bid is more than $2 but does not exceed $5; (iii) no more than .50 where the bid is more than $5 but does not exceed $10; (iv) no more than .80 where the bid is more than $10 but does not exceed $20; and (v) no more than $1 where the bid is more than $20, provided that a Trading Official may establish differences other than the above for one or more series or classes of options.

Requiring that a bid-ask spread meet specified differentials before an Auction can proceed is based on the current OX Opening Process, which requires the bid-ask differential for a series to be in an acceptable range. The proposed differential spread for the Pillar Auction Process is based on the bid-ask differentials currently set forth in Rule 6.37–O(b)(4) with a difference that for Auctions on Pillar, for option contracts with a bid of $2, the differential will be .25 instead of .40. The Exchange believes that including the proposed bid-ask differential in the rule governing the Auction Process would promote clarity and transparency in Exchange rules regarding which quotes—both Market Maker quotes on the Exchange and the Away Market NBBO—that the Exchange would use to determine if there is a Legal Width Quote. The Exchange also proposes to make a conforming change to Rule 6.37–O(c) to add a cross-reference to proposed Rule 6.64P–O(a)(8). This proposed amendment would ensure that the existing procedures for auctions specified in Rule 6.37–O(c) would continue to be available for option symbols that have transitioned to Pillar.

• Proposed Rule 6.64P–O(a)(9) would define the term ''Matched Volume'' to mean the number of buy and sell contracts that can be matched at the Indicative Match Price, excluding IO Orders. This proposed rule text is based on the definition of ''Matched Volume'' set forth in Rule 7.31–E(a)(9) with a non-substantive difference to reference contracts instead of shares and to be clear that the Matched Volume would not include IO Orders.

• Proposed Rule 6.64P–O(a)(10) would define the term ''pre-open state'' to mean the period before a series is opened or reopened and that during the pre-open state, the Exchange would accept Auction-Only Orders, quotes, and orders designated Day or GTC, including orders ranked Priority 3—Non-Display Orders that are not eligible to participate in an Auction. The proposed rule would further provide that the pre-open state for the Core Open Auction would begin at 6:00 a.m. Eastern Time and would end when the Auction Processing Period begins and that during the pre-open state before the Core Open Auction, the Exchange would re-enter orders designated GTC. The proposed rule would also provide that pre-open state for a Trading Halt Auction would begin at the beginning of the trading halt and would end when the Auction Processing Period begins. This proposed definition would be new for Pillar and is designed to distinguish from both the Auction Processing Period and the period when a series is opened for trading. As noted above, this proposed definition would also be used in proposed Rules 6.40P–O, 6.41P–O, and 6.62P–O.

• Proposed Rule 6.64P–O(a)(11) would define the term ''Rotational Quote'' to mean the highest Market Maker bid and lowest Market Maker offer on the Exchange when the Auction Process begins and that during the Auction Process, the Exchange would

update the price and size of the Rotational Quote and a Rotational Quote can be locked or crossed. The Exchange further proposes that if there are no Market Maker quotes, the Rotational Quote would be published with a zero price and size. The Exchange notes that it currently publishes a ''rotational quote'' when it is in the process of opening or reopening a series, *i.e.,* a quote that is comprised only of Market Maker quotes and does not include orders. The Exchange proposes a difference on Pillar because currently, if the Market Maker Quotes are crossed, the Exchange flips the bid and offer prices. In Pillar, the Exchange would publish a Rotational Quote with the actual bid and offer prices, even if crossed.

Auction Ranking. Proposed Rule 6.64P–O(b) would describe the ranking for Auctions and would provide that orders and quotes on the side of the Imbalance are not guaranteed to participate in the Auction and would be ranked in price-time priority under proposed Rule 6.76P–O consistent with the priority ranking associated with each order or quote, provided that: (1) Limit Orders, quotes, and LOO Orders would be ranked based on their limit price and not the price at which they would participate in the Auction; (2) MOO Orders would be ranked Priority 1—Market Orders; (3) LOO Orders would be ranked Priority 2—Display Orders; and (4) IO Orders would be ranked based on time among IO Orders, subject to eligibility to participate at the Indicative Match Price based on their limit price.

This proposed rule is based on current Rule 6.62–O(b)(B), which provides that orders and quotes in the system will be matched up with one another based on price-time priority. The Exchange proposes a difference in Pillar that orders in the same priority category as quotes would not have priority over Market Maker quotes at the same price, which is current functionality.[51] Instead, orders and Market Marker quotes in the same priority category would be ranked based on time, consistent with proposed Rule 6.76P–O. Because the Exchange proposes that orders and quotes in an options Auction would be processed in the same manner as on its cash equity platform, including that orders on the side of the Imbalance would not be guaranteed to participate in an Auction, the remaining rule text is based in part on Rule 7.35–E(a)(6)(A)—(D), with differences to reflect options trading and to be clear that IO Orders would be ranked on working time among IO Orders, subject to such orders' eligibility to participate at the Indicative Match Price based on their limit price.[52]

Auction Imbalance Information. Proposed Rule 6.64P–O(c) would provide that Auction Imbalance Information would be updated at least every second until the Auction is conducted, unless there is no change to the information and that the Exchange would begin disseminating Auction Imbalance Information at the following times: (1) Core Open Auction Imbalance Information would begin at 8:00 a.m. Eastern Time; and (2) Trading Halt Auction Imbalance Information would begin at the beginning of the trading halt. Because the Exchange proposes to disseminate Auction Imbalance Information for its options market in the same manner that such information is disseminated for its cash equity market, this proposed rule text is based in part on Rule 7.35–E(a)(4)(A) and (C).

Auction Process. Proposed Rule 6.64P–O(d) would set forth the Exchange's proposed Auction Process on Pillar. Similar to current functionality, a series would not be opened or reopened for trading if there is no Legal Width Quote. The Exchange proposes to add on Pillar that a series should also have Market Maker quotes and the Exchange proposes to provide time for this requirement to be established, and if not established within those time frames, providing for a mechanism to open or reopen a series even if there are no Market Maker quotes.

Proposed Rule 6.64P–O(d)(1) would concern the Rotational Quote and would provide that when the Exchange receives the Auction Trigger for a series, the Exchange would send a Rotational Quote to both OPRA and proprietary data feeds indicating that the Exchange is in the process of transitioning from a pre-open state to continuous trading for that series.

Proposed Rule 6.64P–O(d)(2) would provide that once a Rotational Quote has been sent, the Exchange would conduct an Auction when there is both a Legal Width Quote and, if applicable, Market Maker quote with a non-zero offer in the series (subject to the Opening MMQ Time Parameter requirements specified in proposed Rule 6.64P–O(d)(3)). The proposed rule would further provide that the Exchange would wait a minimum of two milliseconds after the Rotational Quote has been sent before an Auction can be conducted. This proposed rule text is designed to provide transparency and determinism in Exchange rules of the earliest potential time that a series could be opened after the Exchange receives an Auction Trigger, and subject to the series meeting all other requirements for opening or reopening.

Proposed Rule 6.64P–O(d)(2)(A) would provide that if there is Matched Volume that can trade at or within the Auction Collars, the Auction would result in a trade at the Indicative Match Price. Proposed Rule 6.64P–O(d)(2)(B) would provide that if there is no Matched Volume that can trade at or within the Auction Collars, the Exchange would transition to continuous trading as described in proposed Rule 6.64P–O(f) below and the Auction would result in a quote. This proposed rule text is designed to provide transparency of when an Auction would result in a trade or a quote.

Proposed Rule 6.64P–O(d)(3) would specify the Opening MMQ Time Parameter. As proposed, once the Auction Process begins, the Exchange would begin a one-minute timer for the Market Maker(s) assigned to a series to submit a quote with a non-zero offer. This one-minute timer would be the Opening MMQ Time Parameter. The Opening MMQ Time Parameter is designed to provide the Market Makers assigned to a series an opportunity to submit a quote, and provide transparency in Exchange rules of the circumstances of when the Exchange would open a series for trading if the assigned Market Maker(s) does not submit a quote within the specified time periods, as follows:

- Proposed Rule 6.64P–O(d)(3)(A) would provide that if there are no Market Makers assigned to a series, the Exchange would conduct an Auction in that series based on only a Legal Width Quote, without waiting for the Opening MMQ Time Parameter to end.
- Proposed Rule 6.64P–O(d)(3)(B) would provide that if there is only one Market Maker assigned to a series:
  - The Exchange would conduct the Auction, without waiting for the Opening MMQ Time Parameter to end, as soon as there is both a Legal Width Quote and the assigned Market Maker has submitted a quote with a non-zero offer (proposed Rule 6.64P–O(d)(3)(B)(i)).
  - If the Market Maker has not submitted a quote with a non-zero offer by the end of the Opening MMQ Time Parameter and there is a Legal Width Quote, the Exchange would conduct the

[51] Current Rule 6.64–O(b)(B) provides that ''orders will have priority over Market Maker quotes at the same price.''

[52] *See* discussion *supra,* regarding proposed Rule 6.62P–O(c)(3) and how IO Orders would function.

Auction (proposed Rule 6.64P–O(d)(3)(B)(ii)).

• Proposed Rule 6.64P–O(d)(3)(C) would provide that if there are two or more Market Makers assigned to a series:

○ The Exchange would conduct the Auction, without waiting for the Opening MMQ Time Parameter to end, as soon as there is both a Legal Width Quote and at least two assigned Market Makers have submitted a quote with a non-zero offer (proposed Rule 6.64P–O(d)(3)(C)(i)).

○ If at least two Market Makers have not submitted a quote with a non-zero offer by the end of the Opening MMQ Time Parameter, the Exchange would begin a second Opening MMQ Time Parameter and that during the second Opening MMQ Time Parameter, the Exchange would conduct the Auction, without waiting for the second Opening MMQ Time Parameter to end, if there is both a Legal Width Quote and at least one Market Maker has submitted a quote with a non-zero offer (proposed Rule 6.64P–O(d)(3)(C)(ii)).

○ If no Market Maker has submitted a quote with a non-zero offer by the end of the second Opening MMQ Time Parameter and there is a Legal Width Quote, the Exchange would conduct the Auction (proposed Rule 6.64P–O(d)(3)(C)(iii).

Proposed Rule 6.64P–O(d)(4) would provide that for the first five minutes of the Auction Process, if there is no Legal Width Quote, the Exchange would not conduct an Auction, even if there is Matched Volume. This proposed rule text provides transparency that when there is Matched Volume, the Exchange would not open a series if there is no Legal Width Quote.

The Exchange proposes new functionality for Pillar to allow the Exchange to open a series when there is a Calculated NBBO wider than the Legal Width Quote, provided that there is also no Matched Volume. As proposed, five minutes after the Auction Process begins:

• Proposed Rule 6.64P–O(d)(4)(A) would provide that if there is no Matched Volume and the Calculated NBBO is wider than the Legal Width Quote, is not crossed, and does not contain a zero offer, the Exchange would transition to continuous trading as described in paragraph (f) of this Rule. As further proposed, in such case, the Auction would result in a quote, provided that there may be an Auction trade even if there is no Legal Width Quote if orders or quotes arrive during the period when the Exchange is evaluating the status of orders and quotes.[53] The Exchange believes this proposed rule would provide an opportunity for more series to open for trading when there is a Calculated NBBO in a series that is wider than the Legal Width Quote and is not crossed and does not contain a zero offer.

• Proposed Rule 6.64P–O(d)(4)(A)(i) would provide that any time a series is opened or reopened when there is no Legal Width Quote, Market Orders and MOO Orders would not participate in the Auction and would be cancelled before the Exchange transitions to continuous trading.

• Proposed Rule 6.64P–O(d)(4)(B) would provide that if the Exchange still cannot conduct an Auction, the Exchange would continue to evaluate both the Calculated NBBO and interest on the Consolidated Book until the earlier of: (i) A Legal Width Quote is established and an Auction can be conducted; (ii) the series can be opened as provided for in proposed Rule 6.64P–O(d)(4)(A); (iii) the series is halted; or (iv) the end of Core Trading Hours. The proposed rule provides transparency that the Exchange would continue to look for an opportunity to open a series based on changes to the Calculated NBBO or orders and quotes on the Consolidated Book.

Proposed Rule 6.64P–O(d)(5) would provide that the Exchange may deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option series or opening or reopening a series when there is no Legal Width Quote, when it believes it is necessary in the interests of a fair and orderly market. This proposed rule is based on Rule 6.64–O(b)(F) and is designed to provide the Exchange with flexibility to open a series even if there is no Legal Width Quote. For example, a Floor Broker may have a two-sided open outcry order. If the series is not opened, that trade could not be consummated. Accordingly, this proposed rule would allow the Exchange to open a series for trading to facilitate open outcry trading.

Order Processing during an Auction Processing Period. As described above, the Auction Processing Period is the abbreviated time period (*i.e.,* generally measured in less than a second) when the Exchange conducts the Auction. For example, if there is a Legal Width Quote, Market Maker quotes, and Matched Volume, the Auction Processing Period is when that Matched Volume will trade at the Indicative Match Price. New orders and quotes received during the Auction Processing Period would not be eligible to participate in an Auction. Because the Exchange will be using the same Pillar auction functionality for options trading that is used for its cash equity market, the Exchange proposes that proposed Rule 6.64P–O(e) would be based on Rule 7.35–E(g) and sub-paragraphs (1) and (2) with differences only to references quotes in addition to orders.

Accordingly, as proposed, during an Auction Processing Period, new order and quote messages received during the Auction Processing Period would be accepted but would not be processed until after the Auction Processing Period. As with Rule 7.35–E(g), for purposes of proposed Rule 6.64P–O(e) and (f), an ''order instruction'' would refer to a request to cancel, cancel and replace, or modify an order or quote.

As proposed, during the Auction Processing Period, order instructions would be processed as follows:

• An order instruction that arrives during the Auction Processing Period would not be processed until after the Auction Processing Period if it relates to an order or quote that was received before the Auction Processing Period. Any subsequent order instructions relating to such order would be rejected (proposed Rule 6.64P–O(e)(1)).

• An order instruction that arrives during the Auction Processing Period would be processed on arrival if it relates to an order that was received during the Auction Processing Period (proposed Rule 6.64P–O(e)(2)).

Transition to Continuous Trading. After the Auction Processing Period concludes, *i.e.,* once the Auction is done, the Exchange transitions to continuous trading. During this transition, the way orders, quotes, and order instructions are processed differs depending on when such messages arrived at the Exchange. Proposed Rule 6.64P–O(f) would describe how the Exchange would transition to continuous trading after the Auction Processing Period concludes, and is based on how the Exchange transitions to continuous trading on its cash equity market following a Trading Halt Auction, as described in Rule 7.35–E(h). The transition to continuous trading would proceed as follows.

Proposed Rule 6.64P–O(f)(1) would provide that orders that are no longer eligible to trade would be cancelled. This proposed rule text is based in part on Pillar terminology used in Rule 7.35–

[53] The Exchange expects this to be a rare race condition that would result when the Exchange receives orders and quotes at virtually the same time it is evaluating whether it can open a series based on a wide Calculated NBBO and that as a result of that race condition, those new orders or quotes are marketable against contra-side interest at the same time that the Exchange concludes, based on interest that had previously been received, that it can open on a quote.

E(h)(1). For options trading, the only orders that would no longer be eligible to trade would be Auction-Only Orders.

Proposed Rule 6.64P–O(f)(2) would provide that order instructions would be processed as follows:

• An order instruction that arrives during the transition to continuous trading or the Auction Processing Period under paragraph (e)(1) of this Rule would be processed in time sequence with the processing of orders and quotes as specified in paragraphs (f)(3)(A) or (B) of this Rule if it relates to an order or quote that was received before the Auction Processing Period or that has already transitioned to continuous trading and any subsequent order instructions relating to such order or quote would be rejected (proposed Rule 6.64P–O(f)(2)(A)). This proposed rule text is based on Rule 7.35–E(h)(2)(A) without any substantive differences. This proposed rule text provides transparency regarding how order instructions that arrived during the Auction Processing Period would be processed if they relate to order or quotes that were received before the Auction Processing Period.

• An order instruction that arrives during the transition to continuous trading would be processed on arrival if it relates to an order or quote that was entered during either the Auction Processing Period or the transition to continuous trading and such order or quote has not yet transitioned to continuous trading (proposed Rule 6.64P–O(f)(2)(B)). This proposed rule text is based on Rule 7.35–E(h)(2)(B) without any substantive differences.

Proposed Rule 6.64P–O(f)(3) would set forth how orders and quotes would be processed during the transition to continuous trading following an Auction. The Exchange proposes that it would process Auction-eligible orders and quotes that were received before the Auction Processing Period and orders ranked Priority 3—Non-Display Orders received before a trading halt as follows:

• Proposed Rule 6.64P–O(f)(3)(A)(i) would provide that Limit Orders and quotes would be subject to the Limit Order Price Check, Arbitrage Check, and Intrinsic Value Check, as applicable. This proposed rule is new for Pillar, and is consistent with the proposed rule changes, described above, regarding when the Limit Order Price Check, Arbitrage Check, and Intrinsic Value Check would be applied against orders and quotes that were received during a pre-open state. The Exchange proposes to apply these checks to orders and quotes before they become eligible for trading or routing during continuous trading.

• Proposed Rule 6.64P–O(f)(3)(A)(ii) would provide that Limit Orders that are not cancelled and Market Orders would be subject to the Trading Collar assigned to it. This proposed rule is also consistent with the proposed changes to Trading Collars, described above, that an order received during a pre-open state would be assigned a Trading Collar after an Auction concludes.

• Proposed Rule 6.64P–O(f)(3)(A)(iii) would provide that orders eligible to route that are marketable against Away Market Protected Quotations would route based on the ranking of such orders as set forth in Rule 6.76P–O(c). This proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(b) with non-substantive differences to use the term ''Away Market Protected Quotations'' instead of ''protected quotations on Away Markets.''

• Proposed Rule 6.64P–O(f)(3)(A)(iv) would provide that after routing eligible orders, orders and quotes not eligible to route that are marketable against Away Market Protected Quotations would cancel. This proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(b) with non-substantive differences to use the term ''Away Market Protected Quotations'' instead of ''protected quotations on Away Markets.''

• Proposed Rule 6.64P–O(f)(3)(A)(v) would provide that once there are no more unexecuted orders marketable against Away Market Protected Quotations, orders and quotes that are marketable against other orders and quotes in the Consolidated Book would trade or be repriced. This proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(c) with a clarifying, non-substantive difference to be clear that an order could be repriced based on this assessment. For example, an ALO Order that would be marketable against a contra-side order or quote on the Consolidated Book would be repriced as provided for in proposed Rule 6.62P–O(e)(2). The Exchange further notes that, similar to the Exchange's cash equity market, the Exchange could transition to continuous trading without any Matched Volume that trades at the Indicative Match Price, and yet still report a trade to OPRA before its first quote.[54] The Exchange would not consider a trade that occurs during the transition to continuous trading to be an Auction trade.

• Proposed Rule 6.64P–O(f)(3)(A)(vi) would provide that Market Orders received during a pre-open state would be subject to the validation specified in proposed Rule 6.62P–O(a)(1)(C). The Exchange notes that because such Market Orders would have been already received by the Exchange, if they fail one of those validations, they would be cancelled instead of rejected. This would be new rule text as compared to the Exchange's cash equity rules to reflect the validations that would be applicable to Market Orders for options trading on Pillar.

• Proposed Rule 6.64P–O(f)(3)(A)(vii) would provide that the display quantity of Reserve Orders would be replenished. This proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(d).

• Proposed Rule 6.64P–O(f)(3)(A)(viii) would describe the last step in this process, which is that the Exchange would send a quote to OPRA and proprietary data feeds representing the highest-priced bid and lowest-priced offer of any remaining unexecuted Auction-eligible orders and quotes that were received before the Auction Processing Period. This proposed rule is based on current cash equity functionality, as set forth in Rule 7.35–E(h)(3)(a)(ii). Although the functionality would be the same for both markets, for options traded on the Exchange, the Exchange proposes to describe this aspect of the process in sequence, and reference both orders and quotes. The Exchange notes that this quote would be different than the Rotational Quote sent at the beginning of the Auction Process as it could be comprised of both orders and quotes.

Proposed Rule 6.64P–O(f)(3)(B) would provide that next, orders ranked Priority 3—Non-Display Orders that were received during a pre-open state would be assigned a new working time in time sequence relative to one another based on original entry time and would be subject to the Limit Order Price Check, Arbitrage Check, and Intrinsic Value Check, as applicable, and if not cancelled, would be traded or repriced. This proposed functionality would be new for Pillar and applicable only for options traded on the Exchange. Even though orders ranked Priority 3—Non-Display Orders would not be eligible to trade in an Auction (other than the reserve interest of Reserve Orders), the Exchange proposes to accept such orders during a pre-open state. These orders would transition to continuous trading after orders and quotes that were eligible to trade in an Auction would have transitioned to continuous trading, as described above in proposed Rule 6.64P–O(f)(3)(A)(i)–(viii). The Exchange believes that waiting to process non-displayed orders in this sequence would ensure that there is an NBBO against

[54] For example, as described in proposed Rule 6.62P–O(d)(4)(A), if there is no Legal Width Quote, after five minutes, the Exchange could open a series for trading if there is no Matched Volume and would transition to continuous trading as described in proposed Rule 6.62P–O(f).

which such orders could be priced, as described in proposed Rule 6.62P–O(d) above.

Proposed Rule 6.64P–O(f)(3)(C) would provide that next, orders and quotes that were received during the Auction Processing Period would be assigned a new working time in time sequence relative to one another based on original entry time and would be subject to the Limit Order Price Check, Pre-Trade Risk Controls, Arbitrage Check, Intrinsic Value Check, and validations specified in proposed Rule 6.62P–O(a)(1)(A), as applicable, and if not cancelled would be processed consistent with the terms of the order or quote. This proposed rule text is designed to reflect that even though orders and quotes were received during the Auction Processing Period, they would not be subjected to these validations until after the Exchange has transitioned to continuous trading, and that if they fail these validations, such orders or quotes would be cancelled instead of rejected. This proposed rule text is based in part on Rule 7.35–E(h)(3)(B) with differences to reflect the validations that would be applicable to orders and quotes for options trading.

Proposed Rule 6.64P–O(f)(3)(D) would further provide that when transitioning to continuous trading:

- The display price and working price of orders and quotes would be adjusted based on the contra-side interest in the Consolidated Book or Away Market NBBO, as provided for in Rule 6.62P–O (proposed Rule 6.64P–O(f)(3)(D)(i)). This proposed rule is based in part on Rule 7.35–E(h)(3)(C) with differences to reflect that for options trading, the display price or working price of an order may be adjusted based either on contra-side interest on the Consolidated Book or the Away Market NBBO.
- The display price and working price of a Day ISO would be adjusted in the same manner as a Non-Routable Limit Order until the Day ISO is either traded in full or displayed at its limit price and the display price and working price of a Day ISO ALO would be adjusted in the same manner as an ALO Order until the Day ISO ALO is either traded in full or displayed at its limit price (proposed Rule 6.64P–O(f)(3)(D)(ii)). This proposed rule is based in part on Rule 7.35–E(h)(3)(D) with differences to reflect how a Day ISO ALO would be processed.

Proposed Rule 6.64P–O(g) would describe order processing during a trading halt. The proposed rule is based in part on Rule 7.18–E(c) with differences to reflect how options would trade on Pillar. As proposed, the Exchange would process new and existing orders and quotes in a series during a trading halt as follows:

- Maintain any unexecuted portion of orders ranked Priority 3—Non-Display Orders (proposed Rule 6.64P–O(g)(1)). This proposed rule would be unique to options traded on the Exchange because the Exchange cancels non-displayed orders on its cash equity market during a trading halt (see, *e.g.,* Rule 7.18–E(c)(1)).
- Cancel any unexecuted quantity of orders displayed at a Trading Collar and Market Maker quotes (proposed Rule 6.64P–O(g)(2)). This proposed rule would be unique for options traded on the Exchange. The Exchange proposes to cancel resting Market Maker quotes during a trading halt, but as noted below, would accept new Market Maker quotes during a trading halt, which would be the basis for the Rotational Quote that would be published for a Trading Halt Auction. The Exchange also proposes to cancel any unexecuted quantity of orders displayed at a Trading Collar because such orders would have already been subject to a 500-millisecond timer, which would have ended during a trading halt.
- Re-price all other resting orders on the Consolidated Book to their limit price. The repricing of a Non-Routable Limit Order, ALO Order, or Day ISO ALO to its limit price during a trading halt would not be counted toward the number of times such order may be repriced and any subsequent repricing of such order during the transition to continuous trading would be permitted as the additional repricing event as provided for in Rule 6.62P–O(e)(1)(B) and (e)(2)(C) (proposed Rule 6.64P–O(g)(3)). As described above, once resting, a Non-Routable Limit Order, ALO Order, or Day ISO ALO that was repriced on arrival is eligible to be repriced only one additional time. This proposed rule provides transparency that the repricing of such orders to their limit price during a trading halt would not count towards that ''one'' additional repricing, but that any subsequent repricing after the Auction concludes would count.
- Accept and process all cancellations (proposed Rule 6.64P–O(g)(4)). This proposed rule is based on Rule 7.18–E(c)(4) without any differences.
- Reject Incoming Limit Orders designated IOC or FOK (proposed Rule 6.64P–O(g)(5)). This proposed rule is based in part on Rule 7.18–E(c)(5) with a difference to add orders designated FOK and not include non-displayed orders.
- Accept all other incoming order and quote messages and instructions until the Auction Processing Period for the Trading Halt Auction, at which point, paragraph (e) of proposed Rule 6.64P–O would govern the entry of incoming orders, quotes, and order instructions (proposed Rule 6.64P–O(g)(6)). This proposed rule is based on Rule 7.18–E(c)(6) with non-substantive differences to cross reference the options rule relating to the transition to continuous trading.
- Disseminate a zero bid and zero offer quote to OPRA and proprietary data feeds (proposed Rule 6.64P–O(g)(7)). This proposed rule is based on current functionality and is designed to promote clarity and transparency in Exchange rules that when a trading halt begins, the Exchange will ''zero'' out the Exchange's BBO.

Finally, proposed Rule 6.64P–O(h) would provide that whenever in the judgment of the Exchange the interests of a fair and orderly market so require, the Exchange may adjust the timing of or suspend the Auctions set forth in this Rule with prior notice to ATP Holders. This proposed rule is based on Rule 7.35–E(i) without any differences.

In connection with proposed Rule 6.64P–O, the Exchange proposes to add the following preamble to Rule 6.64–O: ''This Rule will not be applicable to trading on Pillar.'' This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.64–O would not be applicable to trading on Pillar.

As discussed above, because of the technology changes associated with the migration to the Pillar trading platform, subject to approval of this proposed rule change, the Exchange will announce by Trader Update when rules with a ''P'' modifier will become operative and for which symbols. The Exchange believes that keeping existing rules on the rulebook pending the full migration of Pillar will reduce confusion because it will ensure that the rules governing trading on the OX system will continue to be available pending the full migration to Pillar.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[55] in general, and furthers the objectives of Section 6(b)(5),[56] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating

[55] 15 U.S.C. 78f(b).

[56] 15 U.S.C. 78f(b)(5).

transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rules to support Pillar would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rules would promote transparency in Exchange rules by using consistent terminology governing trading on both the Exchange's cash equity and options trading platforms, thereby ensuring that members, regulators, and the public can more easily navigate the Exchange's rulebook and better understand how options trading is conducted on the Exchange.

Generally, the Exchange believes that adding new rules with the modifier ''P'' to denote those rules that would be operative for the Pillar trading platform would remove impediments to and perfect the mechanism of a free and open market and a national market system by providing transparency of which rules would govern trading once a symbol has been migrated to the Pillar platform. The Exchange similarly believes that adding a preamble to those current rules that would not be applicable to trading on Pillar would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote transparency regarding which rules would govern trading on the Exchange during and after the transition to Pillar.

In addition, the Exchange believes that incorporating functionality currently available on the Exchange's cash equity market for options trading would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Exchange would be able to offer consistent functionality across both its options and cash equity trading platforms, adapted as applicable for options trading. Accordingly, with the transition to Pillar, the Exchange will be able to offer additional features to its OTP Holders and OTP Firms that are currently available only on the Exchange's cash equity platform. For similar reasons, the Exchange believes that using Pillar terminology for the proposed new rules would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote consistency in the Exchange's rules across both its options and cash equity platforms.

Definitions and Applicability

The Exchange believes that the proposed amendments to Rule 1.1, including moving definitions from Rule 6.1–O and Rule 6.1A–O to Rule 1.1, would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed changes are designed to promote clarity and transparency in Exchange rules by consolidating into Rule 1.1 definitions relating to both cash equity and options trading. The Exchange believes that the proposed changes to eliminate obsolete definitions and make non-substantive edits to existing definitions would further remove impediments to and perfect the mechanism of a free and open market and a national market system because it would ensure that the definitions used in Exchange rules are updated and consistent. Finally, the Exchange believes that organizing Rule 1.1 alphabetically and eliminating sub-paragraph numbering would make the proposed rules easier to navigate.

The Exchange further believes that proposed new Rule 6.1P–O relating to applicability would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule would include those elements of current Rule 6.1–O that would remain applicable and eliminates duplicative text that would no longer be necessary after the transition to Pillar. The Exchange further notes that proposed Rule 6.1P–O is similar to NYSE American Rule 900.1NY.

Order Ranking and Display

The Exchange believes that proposed new Rule 6.76P–O would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Exchange is not proposing substantive changes to how the Exchange would rank and display orders and quotes on Pillar as compared to the OX system. Rather, the proposed revisions to the Exchange's options trading rules would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed changes are designed to simplify the structure of the Exchange's options rules and use consistent Pillar terminology for both cash equity and options trading, without changing the underlying functionality. For example, the Exchange believes the proposed definitions set forth in Rule 6.76P–O, *i.e.,* display price, limit price, working price, working time, and Aggressing Order/Aggressing Quote, would promote transparency in Exchange rules and make them easier to navigate because these proposed definitions would be used in other proposed Pillar options trading rules. The Exchange notes that these proposed definitions are consistent with the definitions set forth in Rule 7.36–E for cash equity trading with differences only as necessary to address functionality associated with options trading that are not applicable to cash equity trading, *e.g.,* reference to quotes.

The Exchange further believes that moving descriptions of order type behavior, which are currently set forth in Rule 6.76–O, to proposed Rule 6.62P–O, and therefore not include such detail in proposed Rule 6.76P–O, would make Exchange rules easier to navigate because information regarding how a specific order type would operate would be in a single location in the Exchange's rulebook. The Exchange notes that this proposed structure is consistent with the Exchange's cash equity rules, which similarly set forth information relating to an order type's ranking in Rule 7.31–E. Moreover, the Exchange is not proposing any functional changes to how it would rank and display orders and quotes on Pillar as compared to the OX system.

Order Execution and Routing

The Exchange believes that proposed new Rule 6.76AP–O would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule would set forth a price-time priority model for Pillar that is substantively the same as the Exchange's current price-time priority model as set forth in Rule 6.76A–O. The proposed differences as compared to Rule 6.76A–O are designed to use Pillar terminology that is based in part on Rule 7.37–E, if applicable, without changing the functionality that is currently available for options trading.

The Exchange believes that the proposed modifications to the LMM Guarantee would remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides clarity of how multiple quotes from an LMM would be allocated. The Exchange similarly believes that eliminating Directed Order Market Makers and Directed Orders would remove impediments to and perfect the mechanism of a free and open market and a national market system because these features are not currently used on the Exchange, and therefore eliminating Directed Orders and Directed Order

Market Makers would streamline the Exchange's rules. The Exchange notes that the remaining differences in proposed Rule 6.76AP–O relating to the LMM Guarantee are designed to promote clarity and transparency in Exchange rules and would not introduce new functionality.

The Exchange believes that the structure and content of the rule text in proposed Rule 6.76AP–O promotes transparency by using consistent Pillar terminology. The Exchange also believes that adding more detail regarding current functionality in new Rule 6.76AP–O, as described above, would promote transparency by providing notice of when orders would be executed or routed by the Exchange.

Orders and Modifiers

The Exchange believes that proposed new Rule 6.62P–O would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would use existing Pillar terminology to describe the order types and modifiers that would be available on the Exchange's options Pillar trading system. As noted above, the Exchange proposes to offer order types and modifiers that are either based on existing order types available on the OX system as described in Rule 6.62–O, or orders and modifiers available on the Exchange's cash equity trading platform, as described in Rule 7.31–E. The Exchange believes that structuring proposed Rule 6.62P–O based on the structure of Rule 7.31–E would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote transparency and consistency in the Exchange's rulebook.

In addition to the terminology changes to describe the order types and modifiers that are currently available on the Exchange, the Exchange further believes that the order types and modifiers proposed for options trading on Pillar that either differ from order types and modifiers available on the OX system or that would be new would remove impediments to and perfect the mechanism of a free and open market and national market system because:

- Market Orders on Pillar would function similarly to how Market Orders function under current options trading rules, including being subject to Trading Collars, with additional proposed functionality that is designed to ensure that Market Orders do not execute either when there is no prevailing market in a series, or if the displayed prices are too wide to assure a fair and orderly execution of a Market Order. The Exchange believes that the proposed rule describing Market Orders would promote transparency by providing notice of when a Market Order would be subject to such validations.
- The Exchange is not proposing any new or different behavior for Limit Orders than is currently available for options trading on the Exchange, other than the application of Limit Order Price Protection and Trading Collars, which would differ on Pillar. The Exchange believes using Pillar terminology based on Rule 7.31–E(a)(2) to describe Limit Orders would promote consistency and clarity in Exchange rules.
- The proposed Limit Order Price Protection functionality is based in part on the existing ''Limit Order Filter'' for orders and price protection filters for quotes because an order or quote would be rejected if it is priced a specified percentage away from the contra-side NBB or NBO. The proposed Limit Order Price Protection functionality is also based in part on the functionality available on the Exchange's cash equity trading platform, and therefore is not novel. The Exchange believes that using the same mechanism for both orders and quotes would simplify the operation of the Exchange and achieve similar results as the current rules, which is to reject an order or quote that is priced too far away from the prevailing market. The Exchange believes that re-applying Limit Order Price Protection after an Auction concludes would ensure that Limit Orders and quotes continue to be priced consistent with the prevailing market, and that using an Auction Price (if available, and if not available, Auction Collars, and if not available, the NBBO) to assess Limit Orders and quotes after an Auction concludes would ensure that the Exchange would be applying the most recent price in a series in assessing whether such orders or quotes should be cancelled.
- The proposed Trading Collar functionality is based in part on how trading collars currently function on the Exchange because the proposed functionality would create a ceiling or floor price at which an order could be traded or routed. The proposed Pillar Trading Collar functionality is designed to simplify the process by applying a static ceiling price (for buy orders) or floor price (for sell orders) at which such order could be traded or routed that would be applicable to the order until it is traded or cancelled. The Exchange believes that the proposed functionality would provide greater determinism to an OTP Holder or OTP Firm of the Trading Collar that would be applicable to its orders and when such orders may be cancelled if it reaches its Trading Collar.
- The Exchange is not proposing any new or different Time-in-Force modifiers than are currently available for options trading on the Exchange. The Exchange believes using Pillar terminology based on Rule 7.31–E(b) to describe the time-in-force modifiers would promote consistency and clarity in Exchange rules.
- Auction-Only Orders, and specifically, the proposed MOO and LOO Orders, would operate no differently than how ''Opening-Only Orders'' currently function on the OX system. The Exchange proposes non-substantive differences to use Pillar terminology that is based on Rule 7.31–E(c) terminology. The Exchange further believes that offering its IO Order type, which is currently available for Trading Halt Auctions on the Exchange's cash equity platform, for Auctions on the options trading platform would provide OTP Holders and OTP Firms with new, optional functionality to offset an Imbalance in an Auction.
- The Exchange would continue to offer Reserve Orders, AON Orders, Stop Orders, and Stop Limit Orders, which are currently available on the OX system. The proposed differences to Reserve Orders for options trading would harmonize with how Reserve Orders function on the Exchange's cash equity market, with changes as applicable to address options trading (*e.g.,* no round lot/odd lot concept for options trading). The proposed changes to AON Orders would provide greater execution opportunities for such orders by allowing them to be integrated in the Consolidated Book and once resting, trade with incoming orders and quotes. The changes are also based on how orders with an MTS Modifier, which are also conditional orders, function on the Exchange's cash equity market. The proposed differences for Stop Orders and Stop Limit Orders are designed to promote transparency by providing clarity of circumstances when either order may be elected. Finally, the Exchange believes that offering Non-Displayed Limit Orders for options trading on Pillar, which are available on the Exchange's cash equity platform, would provide additional, optional trading functionality for OTP Holders and OTP Firms. The Exchange notes that the proposed Non-Displayed Limit Order would function similarly to how a PNP Blind Order that locks or crosses the contra-side NBBO would be processed because in such circumstances, a PNP Blind Order is not displayed. A Non-Displayed Limit Order would differ from a PNP Blind

Order only because it would never be displayed, even if its limit price doesn't lock or cross the contra-side NBBO.

• The Exchange believes that the proposed orders (and quotes) with instructions not to route (*i.e.,* Non-Routable Limit Order, ALO Order, and ISOs) would streamline the offerings available for options trading on the Exchange by making the functionality the same for both orders and quotes and consolidating the description of non-routable orders and quotes in proposed Rule 6.62P–O(e). The Exchange believes that using Pillar terminology, including order type names, that is based on the terminology used for cash equity trading will promote clarity and consistency across the Exchange's cash equity and options trading platforms. The Exchange believes that the proposed Non-Routable Limit Order is not novel because it is based on how the PNP, RPNP, and MMRP orders and quotes currently function on the OX system. The Exchange believes that the proposed differences would provide OTP Holders and OTP Firms with greater determinism of when such orders or quotes may be repriced or be cancelled, including providing additional opportunities to cancel such orders. Similarly, the proposed ALO Order is not novel because it is based in part on how the RALO and MMLO orders and quotes currently function on the OX system. Finally, the proposed IOC ISO is not novel for options trading on the Exchange. The proposed DAY ISO and DAY ISO ALO functionality would be new for options trading and are based in part on how such order types function in the Exchange's cash equity market. In addition, the proposed DAY ISO functionality is consistent with existing Rule 6.95–O(b)(3), which currently provides an exception to locking or crossing an Away Market Protected Quotation if the OTP Holder or OTP Firm simultaneously routed an ISO to execute against the full displayed size of any locked or crossed Protected Bid or Protected Offer. The Exchange notes that this exception is not necessary for IOC ISOs because such orders would never be displayed at a price that would lock or cross a Protected Quotation; they cancel if they cannot trade. Accordingly, this existing exception in the Exchange's rules contemplates an ISO that would be displayed, which would mean it would need a time-in-force modifier of ''Day.'' In addition, Day ISOs are available for options trading on other options exchanges, and therefore are not novel.[57]

• The Exchange believes that the proposed additional detail defining Complex Orders to define the ''legs'' and ''components'' of such orders would promote transparency in Exchange rules.

• On Pillar, the only electronically-entered crossing orders would be QCC Orders, which is consistent with current functionality. The Exchange believes that the proposed non-substantive differences, including using Pillar terminology and consolidating rule text relating to QCC Orders in proposed Rule 6.62P–O, would promote transparency and clarity in Exchange rules. In addition, the Exchange believes that the proposed descriptions of how a QCC Order priced at the market would be traded would provide transparency regarding at which price such orders would trade.

• The Exchange believes that moving the descriptions of orders available only in open outcry from Rule 6.62–O to proposed Rule 6.62P–O(h) would ensure that these order types remain in the rulebook after the transition to Pillar is complete. For CTB Orders, the Exchange believes that the proposed substantive difference on Pillar to allow a CTB Order to satisfy any displayed interest (including non-Customer interest) at better prices than the latest-arriving displayed Customer interest would increase execution opportunities and achieve the goal of a CTB Order, which is to clear priority on the Consolidated Book for orders executed in open outcry. The Exchange also believes that codifying this order type and the associated regulatory obligations would add clarity and transparency in Exchange rules.

• The proposed Proactive if Locked/Crossed Modifier, STP Modifier, and MTS Modifier are not novel and are based on the Exchange's current cash equity modifiers of the same name. The Exchange believes that extending the availability of these existing modifiers to options trading would provide OTP Holders and OTP Firms with additional, optional functionality that is not novel and is based on existing Exchange rules. The Exchange further believes that extending the availability of STP Modifiers to all orders, and not just Market Maker orders and quotes, would provide additional protections for OTP Holders and OTP Firms.

Market Maker Quotations

The Exchange believes that proposed Rule 6.37AP–O would remove impediments to and perfect the mechanism of a free and open market and a national market system because it is based on current Rule 6.37A–O, with such changes as necessary to use Pillar terminology. The Exchange believes that consolidating functionality for orders and quotes, and cross referencing Non-Routable Limit Orders and ALO Orders in proposed Rule 6.37AP–O, rather than restating how quotations would be processed in proposed Rule 6.37AP–O, would streamline the Exchange's rules and promote transparency and consistency.

Pre-Trade and Activity-Based Risk Controls

The Exchange believes that the proposed Rule 6.40P–O, setting forth pre-trade and activity-based risk controls, would remove impediments to and perfect the mechanism of a free and open market and a national market system and promote just and equitable principles of trade because the proposed functionality would incorporate existing activity-based risk controls, without any substantive differences, and augment them with additional pre-trade risk controls and related functionality that are based on the pre-trade risk controls currently available on the Exchange's cash equity trading platform. The Exchange believes that the proposed differences are designed to provide greater flexibility to OTP Holders and OTP Firms in how to set risk controls for both orders and quotes. In addition, the Exchange believes that aggregating a Market Maker's quotes and orders for purposes of calculating activity-based risk controls would better reflect the aggregate risk that a Market Maker has with respect to its quotes and orders. The proposed kill switch functionality would also provide OTP Holders and OTP Firms with greater flexibility to provide bulk instructions to the Exchange with respect to cancelling existing orders and quotes and blocking new orders and quotes.

Price Reasonability Checks—Orders and Quotes

The Exchange believes that the proposed Rule 6.41P–O, setting forth Price Reasonability Checks, would remove impediments to and perfect the mechanism of a free and open market and a national market system because they are based on existing functionality, with differences designed to use Pillar terminology and promote consistency and transparency in Exchange rules. Specifically, on Pillar, the Exchange proposes to apply the same types of Price Reasonability Checks to both orders and quotes, and therefore proposes to describe those checks in a single rule—proposed Rule 6.41P–O. The proposed rule also provides specificity regarding when the Price

[57] *See supra* notes 39, 40.

Reasonability Checks would be applied to an order or quote, which would promote transparency and clarity in Exchange rules.

Auction Process

The Exchange believes that proposed Rule 6.64P–O would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule maintains the fundamentals of an auction process that is tailored for options trading while at the same time enhancing the process by incorporating Pillar auction functionality that is currently available on the Exchange's cash equity platform, as described in Rule 7.35–E. For example, the Exchange proposes to augment the imbalance information that would be disseminated in advance of an Auction to include fields available on the Exchange's cash equity market (*e.g.,* Book Clearing Price and Far Clearing Price) as well as information specific to options trading (*e.g.,* Auction Collars based on a Legal Width Quote and Auction Indicator). The Exchange believes that the proposed Auction Imbalance Information would promote transparency to market participants in advance of an Auction. The Exchange also proposes to transition to continuous trading following an Auction in a manner similar to how the Exchange's cash equity market transitions to continuous trading following a cash equity Trading Halt Auction, including how orders and quotes that are received during an Auction Processing Period would be processed, which the Exchange believes would promote consistency across the Exchange's options and cash equity trading platforms. Because the Exchange would be harnessing Pillar technology to support Auctions for options trading, the Exchange believes that structuring proposed Rule 6.64P–O based on Rule 7.35–E would promote transparency in the Exchange's trading rules.

The Exchange further believes that the proposed Auction Process for options trading on Pillar would remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed process is based on the current options auction process, including that orders are matched based on price-time priority and that an Auction would not be conducted if the bid-ask differential is not within an acceptable range. As proposed, the Auction Process on Pillar would begin with the proposed Rotational Quote, which would provide notice not only of when the process would begin, but also whether Market Makers on the Exchange have quoted in a series. The Exchange believes that the proposed Opening MMQ Time Parameter would promote transparency in Exchange rules of when the Exchange could open a series, including circumstances of when the Exchange would wait to provide Market Makers time to submit a two-sided quotation in a series and when the Exchange would proceed with opening or reopening a series based on a Legal Width Quote even if there are no Market Maker quotes in that series. The proposed rule would also provide transparency of when the Exchange would open or reopen a series for trading when the Calculated NBBO is wider than the Legal Width Quote for the series. The Exchange believes that the proposed process is designed to provide opportunities for a series to open or reopen, while at the same time preserving the existing requirement that a series would not open on a trade if there is no Legal Width Quote.

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 operates in a competitive market and regularly competes with other options exchanges for order flow. The Exchange believes that the transition to Pillar would promote competition among options exchanges by offering a low-latency, deterministic trading platform. The proposed rule changes would support that inter-market competition by allowing the Exchange to offer additional functionality to its OTP Holders and OTP Firms, thereby potentially attracting additional order flow to the Exchange. Otherwise, the proposed changes are not designed to address any competitive issues, but rather to amend the Exchange's rules relating to options trading to support the transition to Pillar. As discussed in detail above, with this rule filing, the Exchange is not proposing to change its core functionality regarding its price-time priority model, and in particular, how it would rank, display, execute or route orders and quotes. Rather, the Exchange believes that the proposed rule changes would promote consistent use of terminology to support both options and cash equity trading on the Exchange, making the Exchange's rules easier to navigate. The Exchange does not believe that the proposed rule changes would raise any intra-market competition as the proposed rule changes would be applicable to all OTP Holders and OTP Firms, and reflects the Exchange's existing price-time priority model, including existing LMM Guarantee, without proposing any substantive changes.

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–2021–47 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–2021–47. 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–2021–47 and should be submitted on or before July 30, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[58]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–14391 Filed 7–8–21; 8:45 am]

BILLING CODE 8011–01–P

[58] 17 CFR 200.30–3(a)(12).

FEDERAL REGISTER

Vol. 86 Friday,

No. 129 July 9, 2021

Part IV

The President

Notice of July 7, 2021—Continuation of the National Emergency With Respect to Hong Kong

Notice of July 7, 2021—Continuation of the National Emergency With Respect to Transnational Criminal Organizations

Federal Register
Vol. 86, No. 129
Friday, July 9, 2021

Presidential Documents

Title 3—

The President

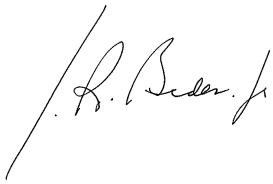
Notice of July 7, 2021

Continuation of the National Emergency With Respect to Hong Kong

On July 14, 2020, by Executive Order 13936, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the situation with respect to Hong Kong.

The situation with respect to Hong Kong, including recent actions taken by the People's Republic of China to fundamentally undermine Hong Kong's autonomy, continues to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared on July 14, 2020, must continue in effect beyond July 14, 2021. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13936 with respect to the situation in Hong Kong.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 7, 2021.

[FR Doc. 2021–14806
Filed 7–8–21; 11:15 am]
Billing code 3295–F1–P

Presidential Documents

Notice of July 7, 2021

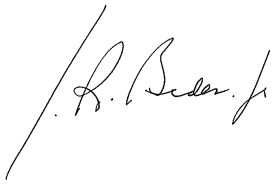
Continuation of the National Emergency With Respect to Transnational Criminal Organizations

On July 24, 2011, by Executive Order 13581, the President declared a national emergency with respect to transnational criminal organizations pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the activities of significant transnational criminal organizations.

On March 15, 2019, by Executive Order 13863, the President took additional steps to deal with the national emergency with respect to significant transnational criminal organizations in view of the evolution of these organizations as well as the increasing sophistication of their activities, which threaten international political and economic systems and pose a direct threat to the safety and welfare of the United States and its citizens, and given the ability of these organizations to derive revenue through widespread illegal conduct, including acts of violence and abuse that exhibit a wanton disregard for human life as well as many other crimes enriching and empowering these organizations.

The activities of significant transnational criminal organizations continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For these reasons, the national emergency declared in Executive Order 13581 of July 24, 2011, under which additional steps were taken in Executive Order 13863 of March 15, 2019, must continue in effect beyond July 24, 2021. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to significant transnational criminal organizations declared in Executive Order 13581.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 7, 2021.

[FR Doc. 2021–14814
Filed 7–8–21; 11:15 am]
Billing code 3295–F1–P

Reader Aids

Federal Register

Vol. 86, No. 129

Friday, July 9, 2021

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, JULY

34905–35216 1
35217–35382 2
35383–35594 6
35595–36060 7
36061–36192 8
36193–36482 9

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10231 35385
Administrative Orders:
Memorandums:
Memorandum of June 29, 2021 35383
Notices:
Notice of July 7, 2021 .....36479, 36481

7 CFR

1710 36193
1714 36193
1717 36193
1718 36193
1721 36193
1726 36193
1730 36193
1767 36193
Proposed Rules:
986 35409

8 CFR

Proposed Rules:
214 35410
248 35410
274a.12 35410

10 CFR

52 34905
Proposed Rules:
52 .....34999, 35023
429 36018
430 .....35660, 35668
431 36018

12 CFR

702 34924
1022 35595
Ch. XII 36199

14 CFR

39 .....34933, 35217, 35387, 35599, 35601, 36061, 36064, 36202, 36205, 36207
71 .....34937, 35221, 36210, 36212
97 .....34938, 34941
Proposed Rules:
39 .....35027, 35410, 35413, 35416, 35690, 35692, 35695, 35697, 36241, 36243
71 .....35233, 35235, 35237, 35419, 35420

15 CFR

744 35389

16 CFR

Proposed Rules:
Ch. I 35239

19 CFR

10 35566
102 35566
132 35566
134 35566
163 35566
182 35566
190 35566
Proposed Rules:
102 35422
177 35422

20 CFR

200 35221
295 34942

24 CFR

11 35391
92 34943

25 CFR

48 34943

27 CFR

9 .....34952, 34955
70 34957

29 CFR

Proposed Rules:
1910 36073

31 CFR

1 35396
Proposed Rules:
33 35156
520 35399

32 CFR

199 36213

33 CFR

100 .....35399, 35604
117 35402
165 .....34958, 34960, 34961, 34963, 34964, 35224, 35225, 35403, 36066, 36067, 36068, 36070
210 35225
214 35226
Proposed Rules:
100 35240
165 35242

34 CFR

686 36070
Ch. II 36217, 36220, 36222

37 CFR

1 .....35226, 35229
2 35229
Proposed Rules:
1 35429

39 CFR

111 35606

Proposed Rules:

Ch. III 36246

40 CFR

52 ....35404, 35608, 35610, 36227

62 35406

Proposed Rules:

52 ....35030, 35034, 35042, 35244, 35247

62 35044

81 35254

42 CFR

510 36229

600 35615

Proposed Rules:

409 35874

413 36322

424 35874

484 35874

488 35874

489 35874

498 35874

512 36322

45 CFR

155 36071

Proposed Rules:

147 35156

155 35156

156 35156

47 CFR

64 35632

73 ....34965, 35231

Proposed Rules:

2 35700

15 ....35046, 35700

74 35046

90 35700

95 35700

48 CFR

204 36229

212 36229

252 36229

501 34966

552 34966

570 34966

Proposed Rules:

615 35257

652 35257

49 CFR

381 35633

382 35633

383 35633

384 35633

385 35633

390 35633

391 35633

Proposed Rules:

385 35443

393 35449

50 CFR

17 34979

300 35653

660 36237

665 36239

Proposed Rules:

17 35708

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List July 8, 2021

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1*

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.