FEDERAL REGISTER

Vol. 87 Wednesday

No. 12 January 19, 2022

Pages 2673–3020

OFFICE OF THE FEDERAL REGISTER

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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.

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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.

OFFICE OF MANAGEMENT AND BUDGET

2 CFR Part 200

Uniform Administrative Requirements, Cost Principles, and Audit Requirements

AGENCY: Office of Management and Budget.

ACTION: Guidance.

SUMMARY: This document announces the availability of the second of two 2021 Compliance Supplement Addenda (2021 Addendum 2) for the Office of Management and Budget's uniform administrative requirements, cost principles, and audit requirements regulations. The first 2021 Addendum 1 was published in the **Federal Register** on December 3, 2021. This document also offers interested parties an opportunity to comment on the 2021 Addendum 2.

DATES: The 2021 Addendum 2 serves as a complement to the 2021 Compliance Supplement published on August 13, 20211 (FR Doc. 2021–17363) and applies to fiscal year audits beginning after June 30, 2020. All comments to the 2021 Addendum 2 must be in writing and received by February 18, 2022. Late comments will be considered to the extent practicable.

ADDRESSES: Comments will be reviewed and addressed, when appropriate, in the 2022 Compliance Supplement. Electronic mail comments may be submitted to: *https://www.regulations.gov.* Please include ''2 CFR part 200 Subpart F—Audit Requirements, Appendix XI—Compliance Supplement Addendum—2021 2'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be sent to: *GrantsTeam@omb.eop.gov.*

Please note that all public comments received are subject to the Freedom of Information Act and will be posted in their entirety, including any personal and/or business confidential information provided. Do not include any information you would not like to be made publicly available.

The 2021 Addendum 2 with Part 4 of the seven programs (described in the **SUPPLEMENTARY INFORMATION** section) is available online on the CFO home page at *https://www.cfo.gov/policies-and-guidance/.*

FOR FURTHER INFORMATION CONTACT: Recipients and auditors should contact their cognizant or oversight agency for audit, or Federal awarding agency, as appropriate under the circumstances. The Federal agency contacts are listed in appendix III of the Supplement. Subrecipients should contact their pass-through entity. Federal agencies can contact the OMB Grants team at *GrantsTeam@omb.eop.gov* or Gil Tran at 202–881–7830.

SUPPLEMENTARY INFORMATION: The 2021 Addendum 2 (2 CFR part 200, subpart F, appendix XI) adds audit guidance for 7 programs to Part 4 of the 2021 Compliance Supplement. This guidance is applicable only for audits with report dates subsequent to issuance of this guidance. Other Parts of the 2021 Compliance Supplement remain unchanged. The programs are:

USDA 10.542—Pandemic EBT—Food Benefits

USDA 10.649—Pandemic EBT—Admin Costs

HHS 93.575—Child Care and Development Block Grant

HHS 93.499—Low Income Household Water Assistance Program

HHS 93.558—TANF

HUD 14.871—Section 8 Housing Choice Vouchers

DOT 20.315—National Railroad Passenger Corporation Grants

Deidre A. Harrison,

Acting Controller.

[FR Doc. 2022–00947 Filed 1–18–22; 8:45 am]

BILLING CODE 3110–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2021–BT–STD–0002]

RIN 1904–AF14

Energy Conservation Program: Product Classes for Residential Dishwashers, Residential Clothes Washers, and Consumer Clothes Dryers

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

ACTION: Final rule.

SUMMARY: On October 30, 2020, and December 16, 2020, the U.S. Department of Energy (''DOE'') published two final rules that established product classes for residential dishwashers with a cycle time for the normal cycle of 60 minutes or less, top-loading residential clothes washers and certain classes of consumer clothes dryers with a cycle time of less than 30 minutes, and front-loading residential clothes washers with a cycle time of less than 45 minutes (''short-cycle product classes''). The rules resulted in amended energy conservation standards for these short-cycle product classes, without determining whether relevant statutory criteria for amending standards were met. On August 11, 2021, DOE published a notice of proposed rulemaking (''NOPR'') to withdraw these short-cycle product classes This final rule finalizes the revocation of the two earlier rules that improperly promulgated standards for these new product classes and reinstates the prior product classes and applicable standards for these covered products.

DATES: The effective date of this rule is February 18, 2022.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, 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-STD-0002. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

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

FOR FURTHER INFORMATION CONTACT: Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Kathryn McIntosh, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 586–2002. Email: *Kathryn.McIntosh@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Summary of the Final Rule

On October 30, 2020, and December 16, 2020, DOE published two final rules that established new short-cycle product classes for residential dishwashers, residential clothes washers, and consumer clothes dryers. 85 FR 68723 (''October 2020 Final Rule''); 85 FR 81359 (''December 2020 Final Rule''); collectively, the ''2020 Final Rules.'' While these short-cycle products had previously been subject to energy and water conservation standards, the 2020 Final Rules created new short-cycle product classes that are not subject to any water or energy conservation standards. 85 FR 68723, 68742; 85 FR 81359, 81376. As a result, products falling into these short-cycle classes are currently allowed to consume unlimited amounts of energy and water.

In amending its standards to allow for short-cycle products that can use unlimited water and energy, DOE had not considered whether the amended standards met the criteria in the Energy Policy and Conservation Act, as amended (''EPCA''),[1] for issuing an amended standard. Notably, among other things, DOE did not determine, as required, that the amended standards for short-cycle products were designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. 42 U.S.C. 6295(o)(2)(A).

On August 11, 2021, DOE published a NOPR (''August 2021 NOPR'') proposing to revoke the 2020 Final Rules. 86 FR 43970. DOE stated that these two rules improperly resulted in new product classes that amended the existing energy conservation standards for these products without determining whether the relevant statutory criteria for amending such standards were met. As a result, DOE proposed to reinstate the prior product classes and applicable standards for these covered products that existed prior to the 2020 Final Rules. *Id.* at 86 FR 43971.

In this final rule, based on the failure of the 2020 Final Rules to consider whether amended standards for the short-cycle products met the EPCA criteria, DOE revokes the 2020 Final Rules and reinstates the prior product classes and applicable standards for these covered products.

II. Authority and Background

A. Authority

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These covered products include residential dishwashers, residential clothes washers, and consumer clothes dryers, the subjects of this document. 42 U.S.C. 6292(a)(6), (7), and (8), respectively.

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including residential dishwashers, residential clothes washers, and consumer clothes dryers. For instance, any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. 42 U.S.C. 6295(o)(2)(A). In deciding whether a standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens by considering the comments received on the proposed rule and, to the greatest extent possible, considering the following seven statutory factors: (1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard; (2) the savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard; (3) the total projected amount of energy (or as applicable, water) savings likely to result directly from imposition of the standard; (4) any lessening of the utility or the performance of the covered products likely to result from imposition of the standard; (5) the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard; (6)

[1] All references to EPCA in this document refer to the statute as amended by the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.

the need for national energy and water conservation; and (7) other factors the Secretary of Energy (''Secretary'') considers relevant. 42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII). Furthermore, the new or amended standard must result in a significant conservation of energy. 42 U.S.C. 6295(o)(3)(B).

EPCA also includes what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. 42 U.S.C. 6295(o)(1).

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

B. Background

As previously described, DOE's 2020 Final Rules amended the applicable energy and water conservation standards for residential dishwashers, residential clothes washers, and consumer clothes dryers in establishing new short-cycle product classes for those products. Creation of those short-cycle classes effectively removed the energy and water conservation standards that had previously applied to those products.

Through its August 2021 NOPR, DOE proposed to revoke the 2020 Final Rules and reinstate the prior product classes and applicable standards for these covered products. 86 FR 43970. DOE received comments in response to the August 2021 NOPR from the interested parties listed in Table II.1.

TABLE II.1—WRITTEN COMMENTS RECEIVED IN RESPONSE TO THE AUGUST 2021 NOPR AND REFERENCED IN THE FINAL RULE

Commenter(s)	Abbreviation used in this final rule	Commenter type
60 Plus Association		Advocates.
Alliance for Water Efficiency	AWE	Efficiency Organization.
Americans for Tax Reform		Advocates.
Appliance Standards Awareness Project (''ASAP''), Alliance for Water Efficiency (''AWE''), American Council for an Energy-Efficient Economy (''ACEEE''), Consumer Federation of America (''CFA''), National Consumer Law Center, on behalf of its low-income clients (''NCLC''), and Northwest Energy Efficiency Alliance (''NEEA'').	Joint Commenters	Efficiency Organizations.
Association of Home Appliance Manufacturers	AHAM	Trade Association.
Attorneys General of California, Colorado, Connecticut, Illinois, Massachusetts, Maryland, Maine, Michigan, Minnesota, New Mexico, Nevada, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia, and the City of New York.	Joint State AGs, DC, and NYC	State Officials.
Attorney General of Missouri, Eric Schmitt	Missouri AG	State Officials.
California Energy Commission	CEC	State Agency.
Competitive Enterprise Institute	CEI	Advocates.
FreedomWorks Foundation		Advocates.
GE Appliances, a Haier Company	GEA	Manufacturer.
Institute for Policy Integrity	IPI	Advocates.
Office of the Arizona Attorney General, Mark Brnovich	Arizona AG	State Officials.
Pacific Gas and Electric Company (''PG&E''), San Diego Gas and Electric (''SDG&E''), and Southern California Edison (''SCE''), collectively, the California Investor-Owned Utilities.	the CA IOUs	Utilities.
Natural Resources Defense Council, Sierra Club, and Earthjustice	NRDC, SC, and EJ	Efficiency Organizations.
Northwest Power and Conservation Council	NWPCC	Interstate Compact Agency.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[3] In addition to the comments listed in Table II.1, DOE also received 246 comments from individuals, which were considered in the development of this final rule and discussed generally in the following sections, but not cited individually.

As discussed in greater detail in the August 2021 NOPR and the following sections, the 2020 rulemakings failed to consider the criteria prescribed under EPCA to amend a standard—specifically, whether the amended standards were designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. 42 U.S.C. 6295(o)(2)(A).

1. Residential Dishwashers

Prior to the October 2020 Final Rule, residential dishwashers were divided into two product classes by size: Standard and compact. Standard size dishwashers had a capacity equal to or greater than eight place settings plus six serving pieces, while compact size dishwashers had a capacity of less than eight place settings plus six serving pieces. 10 CFR 430.32(f)(1) (Oct. 29, 2020 edition). Standard size dishwashers, regardless of normal cycle time,[4] were required to use less than

[3] The parenthetical reference provides a reference for information located in Docket No. EERE–2021–BT–STD–0002, which is maintained at *www.regulations.gov*. The references are arranged as follows: (Commenter name, comment docket ID number, page of that document).

[4] ''Normal cycle'' is the cycle type, including washing and drying temperature options, recommended in the manufacturer's instructions for daily, regular, or typical use to completely wash a full load of normally soiled dishes, including the

Continued

307 kilowatt-hours per year (''kwh/year'') and 5.0 gallons per cycle, while compact dishwashers, regardless of normal cycle time, were required to use less than 222 kwh/year and 3.5 gallons per cycle.

The October 2020 Final Rule replaced an existing product class for standard size residential dishwashers with two new product classes based on cycle time and amended the standards for such dishwashers. 85 FR 68723. DOE initiated the rulemaking in response to a petition for rulemaking submitted by CEI in March 2018, in which CEI asserted that there was considerable consumer dissatisfaction with the dramatically longer cycle time for residential dishwashers under the then-current energy conservation standards. 83 FR 17768 (Apr. 24, 2018). CEI requested that DOE establish a new product class for residential dishwashers with a cycle time of less than one hour. *Id.* at 83 FR 17771.

In the October 2020 Final Rule, DOE stated that a product class of standard size residential dishwashers with a normal cycle of 60 minutes or less would allow manufacturers to provide consumers with the option to purchase a dishwasher that maximizes the consumer utility of a short-cycle time to wash and dry dishes. 85 FR 68723, 68724. DOE also stated that a product class for which the normal cycle time is 60 minutes or less could spur manufacturer innovation to generate additional product offerings to fill the market gap that exists for these products. *Id.* at 85 FR 68726. DOE determined that, under 42 U.S.C. 6295(q), residential dishwashers with a normal cycle time of 60 minutes or less have a performance-related feature that other dishwashers lack and that this feature justifies a separate product class subject to a higher or lower standard than the standards currently applicable to the existing product classes of residential dishwashers. *Id.* As a result, DOE replaced the existing product class for standard size dishwashers with two new product classes for standard size dishwashers based on normal cycle time. DOE kept the existing energy conservation standards for standard size dishwashers with a normal cycle time greater than 60 minutes at the level previously prescribed for the product class that covered all standard size dishwashers. *Id.* at 85 FR 68741. DOE also stated that standard size dishwashers with a normal cycle time of 60 minutes or less were not subject to any energy or water conservation standards, thus allowing for unlimited water and energy usage. *Id.* at 85 FR 68742. DOE based its decision on CEI's petition and the comments the Department received in response to the petition and the proposed rule, as well as additional testing and evaluation conducted by the Department. *Id.* at 85 FR 68723. DOE stated it would consider further amending energy and water conservation standards for standard size dishwashers with a normal cycle time of 60 minutes or less in a future rulemaking. *Id.* at 85 FR 68724.

On December 29, 2020, NRDC, Sierra Club, Consumer Federation of America, and Massachusetts Union of Public Housing Tenants petitioned the U.S. Court of Appeals for the Second Circuit to review and set aside the October 2020 Final Rule. *Natural Resources Defense Council* v. *U.S. Dep't of Energy,* No. 20–4256 (2d Cir.). On the same day, the States of California, Connecticut, Illinois, Maine, Michigan, Minnesota, New Jersey, New Mexico, New York, Nevada, Oregon, Vermont, and Washington, the Commonwealth of Massachusetts, the District of Columbia, and the City of New York filed a separate petition for review of the October 2020 Final Rule in the U.S. Court of Appeals for the Second Circuit. *California* v. *U.S. Dep't of Energy,* No. 20–4285 (2d Cir.). These two cases have been consolidated in the Second Circuit and have been placed in abeyance pending DOE's review of the October 2020 Final Rule.

Further, on March 1, 2021, AHAM petitioned DOE to reconsider the October 2020 Final Rule that established and amended standards for short-cycle residential dishwashers. ''AHAM Petition for Reconsideration-1''; Docket EERE–2021–BT–STD–0002, No. 001 at p. 2.[5] On April 28, 2021, the NRDC, Sierra Club, the Consumer Federation of America, and the Massachusetts Union of Public Housing Tenants (''NRDC *et al.*'') also submitted a petition for DOE to repeal the same October 2020 Final Rule (''NRDC Petition for Reconsideration'').[6] This petition challenged the legality of the final rule, stating that the creation of the new product class violated the core requirements of EPCA. NRDC Petition for Reconsideration, Docket EERE–2021–BT–STD–0002, No. 003 at p. 2. The petition contended that addressing those defects is critical to preventing such an error from being repeated in the future.

2. Residential Clothes Washers and Consumer Clothes Dryers

Prior to the December 2020 Final Rule, product classes for residential clothes washers were based on clothes container capacity and axis of loading—*i.e.,* front-loading or top-loading. 10 CFR 430.32(g)(4) (Dec. 15, 2020 edition). And, prior to the December 2020 Final Rule, product classes for consumer clothes dryers were based on fuel source (120 volt (''V'') electric, 240V electric, or gas), venting configuration (vented or ventless), capacity, and integration with a clothes washer (combination washer-dryer). 10 CFR 430.32(h)(3) (Dec. 15, 2020 edition). Each product class was subject to a specific energy or energy and water conservation standard that applied regardless of the cycle time.

In August 2020, DOE proposed to replace the existing product classes with new product classes based on cycle time for top-loading standard residential clothes washers (30 minutes or greater; less than 30 minutes), front-loading standard residential clothes washers (45 minutes or greater; less than 45 minutes), and vented electric standard and vented gas consumer clothes dryers (30 minutes or greater; less than 30 minutes). 85 FR 49297, 49311–49312 (Aug. 13, 2020) (''August 2020 NOPR''). Unlike the residential dishwasher product class rulemaking, this rulemaking was not initiated in response to a petition, but instead relied on particular similarities between consumer use of residential dishwashers and residential clothes washers and consumer clothes dryers as the basis for proposing the rulemaking. *Id.* at 85 FR 49298. Shortly thereafter, on December 16, 2020, DOE published the December 2020 Final Rule that replaced the product classes with new product classes based on cycle time and kept the existing energy conservation standards for the new product classes with longer cycle times, while declaring the short-cycle product classes are not currently subject to any energy or water conservation standards, thus allowing for unlimited water and energy usage. 85 FR 81359, 81375–81376.

On January 19, 2021, the States of California, Connecticut, Illinois, Maine, Michigan, Minnesota, New Jersey, New Mexico, New York, Nevada, Oregon, Vermont, and Washington, the

power-dry setting. 10 CFR part 430 subpart B appendix C1 (''Appendix C1''), section 1.12.

[5] AHAM submitted its petition pursuant to the Administrative Procedure Act (''APA''), 5 U.S.C. 551 *et seq.*, which provides, among other things, that ''[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' 5 U.S.C. 553(e). The AHAM petition is available in the docket to this rulemaking, EERE–2021–BT–STD–0002, at *www.regulations.gov.*

[6] NRDC also submitted its petition pursuant to the APA, 5 U.S.C. 553(e), to repeal the final rule. The NRDC petition is available in the docket to the is rulemaking, EERE–2021–BT–STD–0002, at *www.regulations.gov.*

Commonwealth of Massachusetts, the District of Columbia, and the City of New York filed a petition for review of the December 2020 Final Rule in the Second Circuit. *California* v. *U.S. Dep't of Energy,* No. 21–108 (2d Cir.). Shortly thereafter, two other groups of petitioners filed petitions for review of the December 2020 Final Rule. The AWE, the U.S. Public Interest Research Group, and Environment America (''AWE, *et al.*'') filed a petition for review of that final rule in the Seventh Circuit on January 17, 2021, and the Sierra Club filed a petition for review of that final rule in the Ninth Circuit on February 12, 2021. *Alliance for Water Efficiency* v. *U.S. Dep't of Energy,* No. 21–428 (2d Cir.); *Sierra Club* v. *U.S. Dep't of Energy,* No. 21–564 (2d Cir.). After transfer of the Seventh and Ninth Circuit petitions for review, all three cases were consolidated in the Second Circuit. In its court filings, AWE, *et al.* raised the following issues with the December 2020 Final Rule: (1) That DOE lacks authority to exempt a product group from water conservation standards; (2) that DOE failed to comply with the requirements for a section 325(q) (42 U.S.C. 6295(q)) rule; (3) that DOE violated EPCA's anti-backsliding provision; and (4) that DOE violated the National Environmental Policy Act. Briefing on the merits is currently stayed through February 1, 2022, while DOE reviews the December 2020 Final Rule.

On April 2, 2021, AHAM further petitioned DOE to reconsider the December 2020 Final Rule that established and amended standards for short-cycle residential clothes washers and consumer clothes dryers. ''AHAM Petition for Reconsideration-2''; Docket EERE–2021–BT–STD–0002, No. 002 at p. 2.[7] AHAM argued that the short-cycle product classes were neither justified nor needed for three reasons. First, AHAM stated that many residential clothes washers and consumer clothes dryers already offer cycles that are within the December 2020 Final Rule's cycle time goal and that meet the existing standards. *Id.* at pp. 7–8, 12. Second, AHAM argued that the cycle times in the December 2020 Final Rule were arbitrary because DOE lacked the data necessary to demonstrate a consumer desire for the times adopted. *Id.* at p. 13. Third, AHAM specified that establishing the separate product classes would likely cause negative, unintended consequences such as stranded manufacturer investments; create new regulation; introduce manufacturer uncertainty until standards for the new product classes are developed; increase test burden; and potentially cause disharmony in North America for residential clothes washer and consumer clothes dryer standards. *Id.* at pp. 8–9, 16–18. For these reasons, AHAM requested that DOE withdraw the December 2020 Final Rule. *Id.* at p. 19.

Like its petition regarding the short-cycle product class for residential dishwashers, AHAM requested that DOE stay the effectiveness of the final rule while considering the petition since the rule allows for unlimited energy and water use by these products. AHAM also asked that DOE issue a statement to the market indicating that these new product classes cannot reliably be used as the basis for new products. *Id.* at p. 2.

III. Discussion

In issuing the 2020 Final Rules, DOE relied on its authority under EPCA to establish product classes with higher or lower levels of energy use or efficiency when prescribing, by rule, an energy conservation standard. 42 U.S.C. 6295(q). In so doing, the 2020 Final Rules also amended the energy conservation standards for the short-cycle product classes by stating they were no longer subject to energy and water conservation standards. 85 FR 68733; 85 FR 81366. But these rules did not address any of EPCA's requirements for amending an energy conservation standard, such as analyzing whether the amended standards are designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. 42 U.S.C. 6295(o)(2)(A); *see* 85 FR 81361. The rules also did not, among other things, adequately consider whether the amended standards violated EPCA's prohibition against prescribing an amended standard that increases the maximum allowable energy use or decreases the energy efficiency of a covered product. 42 U.S.C. 6295(o)(1).

AHAM; GEA; AWE; NWPCC; IPI; NRDC, SC, and EJ; CEC; the CA IOUs; Joint State AGs, DC, and NYC; and Joint Commenters all supported DOE's proposal to revoke the 2020 Final Rules. (AHAM, No. 253 at p.1; GEA, No. 255 at p. 2; AWE, No. 254 at p. 1; NWPCC, No. 9 at p. 1; IPI, No. 244 at p. 1; NRDC, SC, and EJ, No. 243 at p. 1; CEC, No. 245 at pp. 1–2; CA IOUs, No. 247 at p. 1; Joint State AGs, DC, and NYC, No. 249 at p. 1; Joint Commenters, No. 252 at p. 1; ASAP, Public Meeting Transcript, No. 12 at p. 11; AHAM, Public Meeting Transcript, No. 12 at p. 13) AHAM and the CA IOUs specifically requested that DOE finalize its proposed rule as soon as possible. (AHAM, No. 253 at pp. 1–2; CA IOUs, No. 247 at p. 2) AHAM also asserted that doing so would prevent use of the new product classes as the basis for new product offerings and would reduce possibilities for confusion in the market. (AHAM, No. 253 at pp. 1–2;)

CEI, Americans for Tax Reform, FreedomWorks Foundation, the 60 Plus Association, the Arizona AG, and Missouri AG urged DOE to reconsider its proposal to revoke the short-cycle product classes. (CEI, No. 239 at p. 1; Americans for Tax Reform, No. 223 at p. 2; FreedomWorks Foundation, No. 238 at p. 1; 60 Plus Association, No. 251 at p. 1; Arizona AG, No. 248 at p. 1; Missouri AG, No. 246 at p. 1)

Of the 246 comments received from individuals, approximately 46 percent opposed any type of regulation for residential dishwashers, residential clothes washers, or consumer clothes dryers (*e.g.,* ''Please stop making regulations about appliances. The regulations are driving us crazy!'' (Cooksey, No. 37, at p. 1); ''Leave our appliances as is. No new Regulations now or ever!'' (Bise, No. 52, at p. 1); ''We do not need more regulations. Companies have enough regulatory constraints to deal with already. Why burden them with more by making appliances less efficient.'' (Qualls, No. 61, at p. 1)). An additional 39 percent of the individuals expressed concern with cycle times and generally supported short-cycle product classes (*e.g.,* ''Please make household appliances so that they work quickly and efficiently, and so that they are not disposable. It's better for the environment if I keep the appliances for 20 years and they work with minimal maintenance and wear and tear.'' (Anonymous, No. 17 at p. 1); ''Please leave the dishwashers which clean dishes in 1 hour very well alone. I do not want a dishwasher which takes 2–3 hours to clean dishes and uses much more water and energy.'' (Sieben, No, 48 at p. 1); ''Please don't change the dishwasher rules again! If one has to run the dishwasher twice to get the dishes clean, we are not saving any water or electricity!'' (Spurlock; No. 56 at p. 1). The remaining 15 percent of individual commenters included general complaints, but did not specifically comment about the regulations or product classes for residential dishwashers, residential clothes washers, and consumer clothes dryers (*e.g.,* ''Keep dishwasher [*sic*] safe. Keep

[7] As with its first petition, AHAM submitted its second petition pursuant to the APA. The AHAM Petition for Reconsideration-2 is available in the docket to this rulemaking, EERE–2021–BT–STD–0002, at *www.regulations.gov.*

energy prices low.'' (Sith, No. 49 at p. 1); ''My new dishwasher doesn't clean like old one.'' (Hall, No. 106 at p. 1); ''Enough is enough.'' (Mudaro, No. 242 at p. 1)

DOE received numerous comments discussing the concern that this rulemaking would create longer cycle times for residential dishwashers, residential clothes washers, and consumer clothes dryers. DOE is clarifying that this rulemaking does not change the cycle times currently available on the market nor does it change the cycle options available on these products.

The following sections discuss and address the issues raised by commenters in response to the initial determination and proposed amendments in the August 2021 NOPR.

A. Comments on DOE's Statutory Authority

1. Interpretation of 42 U.S.C. 6295(o)(2)(A)

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including residential dishwashers, residential clothes washers, and consumer clothes dryers. EPCA specifies that any new or amended energy conservation standard for any type of covered product shall be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. 42 U.S.C. 6295(o)(2)(A). In the 2020 Final Rules, DOE stated that it would consider establishing energy conservation standards for the new established product classes in subsequent rulemakings. 85 FR 68723, 68724; 85 FR 81359, 81360. As stated in the August 2021 NOPR, the plain meaning of the statutory term ''amend'' is to ''alter formally by adding, deleting or rephrasing.'' (American Heritage Dictionary for the English Language 42 (1981)). The 2020 Final Rules altered the existing energy and water conservation standards for the short cycle products by removing the standards applicable to those products to allow for unlimited energy and water use. This activity clearly fits within this scope of the definition of ''amend'' because DOE deleted the applicable standards altogether. 86 FR 43970, 43973.

Further, in the August 2021 NOPR, DOE stated that even assuming that EPCA were ambiguous in this regard, DOE's position—that the 2020 Final Rules improperly amend the energy and water conservation standards for the short-cycle products—is the better understanding of the statute. Prior to the 2020 Final Rules, the short-cycle products belonged to product classes subject to specific energy and/or water conservation standards. The 2020 Final Rules separated the products that met the classification for the new short-cycle product classes from their regulated counterparts to established product classes not subject to any standard and that could operate with unlimited energy and water use. Those products now do not have any applicable standard, which effectively amended the prior energy or water conservation standards for those products to zero. But the 2020 Final Rules did so without considering any of EPCA's requirements for such action. 86 FR 43970, 43973.

CEC, AWE, IPI, and the Joint Commenters explained that when amending standards, DOE is required to consider whether the standard meets EPCA's criteria for amending a standard, whether the standard is designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (CEC, No. 245 at p. 3; AWE, No. 254 at p. 3; Joint Commenters, No. 252 at pp. 1–2; IPI, No. 244 at p. 1) Further, CEC, IPI, and AWE stated that DOE failed to consider those criteria in the 2020 Final Rules. (CEC, No. 245 at p. 3; AWE, No. 254 at p. 3; IPI, No. 244 at p. 1) AWE also stated that the 2020 Final Rules did not even attempt such an analysis, and it is hard to see how an analysis under paragraph (o)(2) could have supported the Rule as the previous standards were, clearly, technologically feasible and economically justified. (AWE, No. 254 at p. 3)

AWE, IPI, CEC, Joint State AGs, DC, and NYC and the Joint Commenters asserted that the 2020 Final Rules violated EPCA because DOE did not include an analysis of whether the amended standards are designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified as required under 42 U.S.C. 6295(o)(2)(A). (AWE, No. 254 at p. 3; IPI, No. 244 at p. 1; CEC, No. 243 at p. 3; Joint State AGs, DC, and NYC, No. 249 at pp. 5–6; Joint Commenters, No. 252 at pp. 1–2) AWE further commented that a standard that allows unlimited energy and water use would not be justified under EPCA because the standards that existed prior to the creation of the short-cycle product classes were technologically feasible and economically justified and have been used to certify residential dishwashers, residential clothes washers, and consumer clothes dryers for years. (AWE, No. 254 at p. 3) CEC further commented that in issuing the 2020 Final Rules, DOE also disregarded the provision at 42 U.S.C. 6295(o)(2)(B)(i), which requires DOE to consider economic impacts on consumers and manufacturers, savings in operating cost versus increases in price, total projected energy or water savings, and other relevant factors. (CEC, No. 245 at p. 3)

Upon reconsideration, DOE agrees with the commenters that DOE was required to address EPCA's requirements for establishing or amending an energy conservation standard in the 2020 Final Rules, which lacked any analysis of whether the standards were designed to achieve the maximum improvement in energy efficiency that was technologically feasible and economically justified. 42 U.S.C. 6295(o)(2)(A). Further, as discussed at the beginning of this section, applying the plain meaning of the term ''amend,'' DOE altered the existing energy and water conservation standards for short-cycle products in the 2020 Final Rules. Thus, DOE has determined that by stating that the new product classes were not subject to any energy or water conservation standards without following 42 U.S.C. 6295(q), the 2020 Final Rules amended the existing standards in violation of EPCA.

2. Interpretation of 42 U.S.C. 6295(o)(1)

EPCA also specifies that the Secretary may not prescribe any amended standard which increases the maximum allowable energy use of a covered product. 42 U.S.C. 6295(o)(1). This is generally referred to as the ''anti-backsliding'' provision.

AWE; NRDC, SC, and EJ; the CA IOUs; CEC; Joint State AGs, DC, and NYC; and Joint Commenters stated that the 2020 Final Rule violated EPCA's anti-backsliding provision. (AWE, No. 254 at pp. 2–3; NRDC, SC, and EJ, No. 243 at p. 2; CA IOUs, No. 247 at p. 2; CEC, No. 245 at pp. 1–2; Joint State AGs, DC, and NYC, No. 249 at pp. 4–5; CA IOUs, Public Meeting Transcript, No. 12 at p. 12) IPI and the Joint Commenters stated that the 2020 Final rules amended the applicable efficiency standards without considering the prohibition on backsliding. (IPI, No. 244 at p. 1; Joint Commenters, No. 252 at pp. 1–2) CEC stated that the 2020 Final Rules violate EPCA's anti-backsliding prohibition. (CEC, No. 245 at pp. 1–2) CEC further supported what is described as ''DOE's strong repudiation of the previous unlawful rationale that the anti-backsliding prohibition did not apply because the standards were merely being ''deferred'' for these products.'' (CEC, No. 245 at p. 4) NRDC,

SC, and EJ commented that the plain language of the anti-backsliding provision allows no exceptions and serves an important purpose, referring to a House Report, ''to maintain a climate of relative stability with respect to future planning by all interested parties.'' (NRDC, SC, and EJ, No. 243 at p. 2; *citing* House Report 100–11, at 22 (Mar. 3, 1987) Moreover, NRDC, SC, and EJ explained that the U.S. Court of Appeals for the Second Circuit stated in *NRDC* v. *Abraham,* the anti-backsliding provision must be interpreted in light of ''the appliance program's goal of steadily increasing the energy efficiency of covered products'' and congressional intent to provide a ''sense of certainty on the part of manufacturers as to the required energy efficiency standards.'' (NRDC, SC, and EJ, No. 243 at p. 2; *citing NRDC* v. *Abraham,* 355 F.3d 179, 197 (2d Cir. 2004))

Joint State AGs, DC, and NYC stated that while DOE had argued that the product class provision conditioned the anti-backsliding provision in the 2020 Final Rules, the contrary reading is more appropriate in light of the provisions themselves, the canons of statutory interpretation, and EPCA's legislative history, in which the anti-backsliding provision was adopted after the product class provisions. (Joint State AGs, DC, and NYC, No. 249 at pp. 4–5) NRDC, SC, and EJ further discussed this and stated that the anti-backsliding provision constrains DOE's creation of new product classes under EPCA section 325(q). The product class provision authorizes DOE to determine that the presence of a ''performance-related feature'' in certain products ''justifies the establishment of a higher or lower standard'' than the one that ''applies (or will apply)'' to those products. NRDC, SC and EJ explained that in the 2020 Final Rules, DOE used the multiple tenses to argue that DOE can reduce the stringency of a standard, but this interpretation improperly reads the text of the product class provision in a vacuum, ignoring that the statutory context and EPCA's history and purposes must inform the meaning of the words. (NRDC, SC, and EJ, No. 243 at pp. 2–3) NRDC, SC and EJ commented that in light of the statutory context and purpose, the only plausible interpretation is that Congress intended the anti-backsliding provision to constrain DOE's authority under the product class provision, and the broad application of the anti-backsliding provision is consistent with EPCA's goals of ''conserv[ing] energy supplies through energy conservation programs,'' ''provid[ing] for improved energy efficiency of motor vehicles, major appliances, and certain other consumer products,'' and ''conserv[ing] water by improving the water efficiency of certain plumbing products and appliances.'' Further, the ''climate of relative stability'' that Congress sought to ensure would be undermined by a reading of the product class provision that enables DOE to waive the applicability of the anti-backsliding provision as to all existing energy use of efficiency standards for consumer products. (NRDC, SC, and EJ, No. 243 at p. 3)

NRDC, SC, and EJ also noted the history of the product class provision. The 1978 version of the product class provision authorized DOE to ''specify a level of energy efficiency higher or lower than that which applies (or would apply)'' to the product. As enacted in 1978, the product class provision might have been reasonably interpreted to allow for the weakening of existing standards. However, when Congress imposed the anti-backsliding provision on DOE in 1987 and made conforming changes to the product class provision, that amendment altered the degree of discretion conferred in the product class provision. (NRDC, SC, and EJ, No. 243 at p. 3)

DOE agrees with AWE; NRDC, SC, and EJ; the CA IOUs; CEC; Joint State AGs, DC, and NYC; and the Joint Commenters that DOE erred when it did not adequately consider EPCA's anti-backsliding provisions in the 2020 Final Rules.

Joint State AGs, DC, and NYC explained that because Congress had already set minimum standards for residential clothes washers, 42 U.S.C. 6295(g)(9), and residential dishwashers, 42 U.S.C. 6295(g)(10), DOE could only strengthen those standards, consistent with anti-backsliding provision, but the 2020 Final Rules weakened those standards by applying no standards to short-cycle products. Congress did not provide for separate classes for short-cycle products, and the standards thus applied to all such products regardless of that feature. Thus, the Join State AGs, DC, and NYC asserted, the 2020 Final Rules violated EPCA's minimum energy conservation standards for those products. (Joint State AGs, DC, and NYC, No. 249 at pp. 6–7)

DOE agrees with the Joint State AGs, DC, and NYC that because Congress had set standards for residential clothes washers and residential dishwashers that DOE could not weaken those standards without considering EPCA's anti-backsliding provision.

CEI commented that the provision at 42 U.S.C. 6295(o)(1) does not apply to the short-cycle product classes because no standard has yet been established for these new product classes. CEI cited 42 U.S.C. 6291(6) stating that a standard specifies the ''minimum level of energy efficiency or maximum quantity of energy use'' for a covered product. The rulemakings creating these new product classes did not specify a ''minimum level of energy efficiency or maximum quantity of energy use'' for these products. For that reason, the creation of these product classes did not, as defined by the statute, create, modify, or amend any standard for these products. (CEI, No. 239 at p. 5) CEI stated that since 42 U.S.C. 6295(o)(1) only applies to an ''amended standard,'' it does not apply to a new product class for which no standard yet exists. (CEI, No. 239 at p. 5; see also CEI, Public Meeting Transcript, No. 12 at pp. 9–10) CEI further explained that though the lack of a standard does not limit energy and water use of those products, that does not mean that an ''amendment'' of any standard occurred. (CEI, No. 239 at p. 6) CEI stated that those standards still exist today, just as they did before with the exact same water and energy requirements. (CEI, No. 239 at p. 6; see also CEI, Public Meeting Transcript, No. 12 at p. 10) CEI also highlighted other rulemakings where DOE established new product classes without establishing standards for those classes, including distribution transformers in 2007 and beverage vending machines in 2009. CEI stated the fact that no ''first instance of energy conservation standards'' have been issued for faster dishwashers does not undercut the validity of the short-cycle product class for these dishwashers. (CEI, No. 239 at pp. 5–6) CEI argued that the text of 42 U.S.C. 6295(q)(1) explicitly allows a lower standard than applies to other products that do not have that feature and as such, 42 U.S.C. 6295(o)(1) provision does not apply to new product classes when there is no prior standard. (CEI, No. 239 at p. 6)

As explained in the August 2021 NOPR, the October 2020 and December 2020 Final Rules inaccurately cited DOE's 2007 distribution transformer and 2009 beverage vending machine (''BVM'') energy conservation standards rulemakings as support. 85 FR 68723, 68733; 85 FR 81361, 81368. In the 2007 distribution transformers rulemaking, DOE established a separate equipment class for underground mining distribution transformers without establishing associated energy conservation standards. 72 FR 58190 (Oct. 12, 2007). Similarly, in the 2009 BVM rulemaking, DOE established a

separate equipment class for combination BVMs without establishing associated energy conservation standards. 74 FR 44914 (Aug. 31, 2009). But the October 2020 and December 2020 Final Rules failed to note the key distinction between these examples and the short-cycle product class rulemakings. Both the 2007 and 2009 rulemakings were the first instance of energy conservation standards being promulgated for distribution transformers and BVMs. As such, not setting standards for those equipment classes simply maintained the status quo–that is, underground mining distribution transformers and combination BVMs were not subject to energy use or efficiency restrictions either before or after those rulemakings. As a result, DOE did not establish or ''amend'' the standards for these equipment classes and thus was not required to satisfy any of the criteria in EPCA for amending a standard for these equipment classes. 86 FR 43970, 43973–43974.

In contrast, short-cycle residential dishwashers, residential clothes washers, and consumer clothes dryers were all subject to energy conservation standards prior to the October 2020 and December 2020 Final Rules. By stating that short-cycle products were no longer subject to energy or water conservation standards, the October 2020 and December 2020 Final Rules changed the status quo in a direction that would allow for unlimited energy and water use by these short-cycle products. Thus, DOE did ''amend'' the standards for these equipment classes and thus was required to satisfy the requirements in EPCA for issuing an amended standard. 86 FR 43970, 43973–43974.

While CEI is correct that there are not currently any standards applicable to the short-cycle product classes, this ignores the fact that prior to the 2020 Final Rules, products currently defined as short-cycle products were subject to energy conservation and water conservation standards. (*See* 10 CFR 430.32(f), (g), and (h) (Jan. 1, 2020 edition), which prescribed standards for residential dishwashers, residential clothes washers, and consumer clothes dryers, respectively, without regard to cycle time.) As discussed in section III.A.1 of this document, by separating certain models of residential dishwashers, residential clothes washers, and consumer clothes dryers from a product class with standards to a new product class that did not have any applicable standards, DOE amended (or altered) the standards applicable to those models in the 2020 Final Rules. Contrary to CEI's assertions, this is not analogous to the first instance of energy conservation standards for beverage vending machines and distribution transformers, as there were already standards in place for these products. Under the newly-created product classes, these products now have no applicable standard, which allows the energy and water use of these products to be higher than the standard to which they were subjected previously. Accordingly, DOE has concluded that it did not adequately consider EPCA's requirements, including the anti-backsliding provision, when it finalized the 2020 Final Rules.

3. Interpretation of 42 U.S.C. 6295(q)(1)

EPCA provides that, when prescribing an energy conservation standard for a new product class, DOE must specify a different standard level than that which applies generally to a type or class of products for any group of covered products that have the same function or intended use, if DOE determines that products within such group: (A) Consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. 42 U.S.C. 6295(q)(1). In determining whether a performance-related feature justifies such a different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. *Id.*

As stated in the August 2021 NOPR, as support for establishing product classes without associated energy conservation standards, the October 2020 and December 2020 Final Rules asserted that those rules were simply deferring the issuance of new conservation standards. 85 FR 68723, 68733; 85 FR 81359, 81368. As discussed in section III.A.1 of this document, EPCA does not, however, allow DOE to simply defer the establishment of new energy conservation standards for regulated products or equipment that already have energy conservation standards. Even if EPCA authorized deferrals in some instances, any creation of the new product classes here would have needed to follow the requirements of 42 U.S.C. 6295(q), which frames the development of a product class within the context of an energy conservation standard rulemaking. But the October 2020 and December 2020 Final Rules did not develop the new product classes in the context of an energy conservation standard rulemaking. Instead, by stating that the new product classes were not subject to any energy conservation standards without following 42 U.S.C. 6295(q), the October 2020 and December 2020 Final Rules were an amendment in violation of EPCA. 86 FR 43970, 43973.

CEC asserted that although the provision at 42 U.S.C. 6295(q)(1) provides DOE with the authority to establish new product classes, if DOE determines that the sub-class includes a ''performance-related feature [that] justifies the establishment of a higher or lower standard,'' DOE erroneously relied on that authority to justify establishing new product classes and setting lower standards in the 2020 Final Rules. (CEC, No. 245 at p. 4) CEC and IPI stated that the 2020 Final Rules amended the applicable standards without justifying short cycle time as a product utility nor providing any data to justify the creation of a new product class or higher or lower standards. (CEC, No. 245 at p. 4; IPI, No. 244 at p. 1)

The Joint State AGs, DC, and NYC asserted that short-cycle functionality does not provide consumer utility that would qualify as a ''performance-related feature'' consistent with prior interpretations, and, where cycle duration was considered in the past rulemakings, it was not in the product class context. Further, Joint State AGs, DC, and NYC stated that the administrative records compiled in support of the 2020 Final Rules failed to meet either burden, as they did not support DOE's determination that short-cycle functionality was a ''performance-related feature'' as that term is interpreted under EPCA, or that separate standards were necessary to maintain that functionality. The Joint State AGs, DC, and NYC also questioned whether short-cycle functionality provides unique consumer utility and stated that ENERGY STAR data indicated that consumer preferences were more influenced by efficiency and other features of the products instead of cycle time. The Joint State AGs, DC, and NYC concluded that short-cycle time does not qualify as a ''performance-related feature'' that could justify a separate product class with different energy conservation standards under EPCA. (Joint State AGs, DC, and NYC, No. 249 at pp. 6–7) Joint State AGs, DC, and NYC also explained that even if short-cycle functionality could be a performance-related feature under EPCA, DOE did not demonstrate that different energy conservation standards were necessary to provide short-cycle functionality for the subject products. DOE's presumption that weaker energy conservation standards would result in

quicker cycle times was also belied by the data in the rulemaking records, which, when assessed accurately, showed that energy conservation standards did not cause any increase in cycle times. (Joint State AGs, DC, and NYC, No. 249 at p. 7)

Other interested parties cited the availability of short-cycle functionality on existing products as evidence that categorizing normal cycle time as a performance-related feature is unwarranted and unjustified. NWPCC asserted that the residential dishwasher short-cycle product class is unnecessary because, according to a December 2020 NEEA survey, residential dishwasher short-cycles are only used about 8 percent of the time. (NWPCC, No. 9 at p. 2) ASAP, the CA IOUs, and the Joint Commenters stated that the separate product classes are unwarranted and there are already products available on the market with the option of a short cycle. (ASAP, Public Meeting Transcript, No. 12 at p. 11; Joint Commenters, No. 252 at p. 2; CA IOUS, No. 247 at p. 2) NWPCC; AHAM; Joint State AGs, DC, and NYC; and NRDC, SC, and EJ commented that many residential dishwasher, residential clothes washer, and consumer clothes dryer models already provide short-cycle times while meeting the existing standards. (NWPCC, No. 9 at p. 2; AHAM, No. 253 at p. 2; AHAM, Public Meeting Transcript, No. 12 at p. 14; NRDC, SC, and EJ, No. 243 at pp. 3–4; Joint State AGs, DC, and NYC, No. 249 at p. 7) Specifically, the CA IOUs cited data from NEEA, which showed that 76 percent of top-selling residential clothes washers in NEEA's incentive programs, and from AHAM, where over 75 percent of the most popular residential dishwasher models on the market, were equipped with short-cycle options.[8] [9] The CA IOUs further commented that data published by DOE in support of the October 2020 Final Rule [10] demonstrated that, across 29 tested units with a quick-cycle option, the majority of units achieved a higher per-cycle cleaning index score for the quick cycle than for the normal cycle. Accordingly, in their view, the creation of separate product classes is not needed to ensure the availability of quick cycles with adequate cleaning performance, since they are already available to consumers. (CA IOUs, No. 247 at p. 2)

The CA IOUs further commented that cycle time for commonly used appliances may be an important attribute for some consumers, but that cycle time could be incorporated into performance standards, as DOE proposed in the clothes washer test procedure NOPR that DOE published on September 1, 2021. 86 FR 49140. The CA IOUs contended that this approach would create incentives for manufacturers to develop products with a balance of short-cycle times and energy and water efficiency. The CA IOUs further commented that publicly reporting cycle times in DOE's Compliance Certification Management System (''CCMS'') database,[11] as ENERGY STAR already does in its database of qualified products, would provide many consumer information platforms such as Consumer Reports to incorporate and report on cycle time for all DOE-certified appliances, including non-ENERGY STAR products. (CA IOUs, No. 247 at p. 3)

The Joint Commenters specifically noted that, for residential dishwashers, there is wide availability of products that provide the option of a short cycle with a cycle time of less than one hour. The Joint Commenters added that, for residential clothes washers and consumer clothes dryers, DOE's test data [12] showed the availability of products with short cycle times on the normal cycle, which is the cycle that is tested for certification purposes. (Joint Commenters, No. 252 at p. 2) NRDC, SC, and EJ commented that the product class provision at 42 U.S.C. 6295(q) permits DOE to distinguish among classes of products only when products ''have a capacity or other performance-related feature which other products . . . do not have,'' and asserted that this provision in EPCA does not offer limitless discretion to DOE. These commenters noted further that residential dishwashers, residential clothes washers, and consumer clothes dryers are available on the market with cycle options resulting in cycle times shorter than the thresholds in the 2020 Final Rules, indicating that consumers who are concerned about cycle duration can already purchase models that meet their needs. (NRDC, SC, and EJ, No. 243 at pp. 3–4)

AHAM commented that there are not sufficient data to show that a shorter normal cycle time for residential clothes washers and consumer clothes dryers would offer consumer utility that justifies a higher or lower standard. (AHAM, No. 253 at p. 3)

AWE and the Joint State AGs, DC, and NYC asserted that establishing the new short-cycle product classes without simultaneously establishing new standards for them goes against the provision at 42 U.S.C. 6295(q)(1). (AWE, No. 254 at p. 3; Joint State AGs, DC, and NYC, No. 249 at pp. 5–6) AWE commented that the authority on which the 2020 Final Rules relied for creating for creating product classes does not allow a new product class with different water efficiency or usage at all, because section 325(q) applies only to rules that specify ''level[s] of energy use or energy efficiency.'' Thus, according to AWE, DOE had no authority to carve out short-cycle residential clothes washers as a class that can use extra water. AWE added that the central purpose of EPCA, energy and water conservation, would be defeated if DOE were to avoid the statutory limitations set forth by 42 U.S.C. 6295(q)(1) by recharacterizing the amendment of existing standards for the short-cycle products as though it is not an amendment and instead characterizing it as the establishment of new product classes for which prior standards did not exist. (AWE, No. 254 at p. 3)

Americans for Tax Reform argued that DOE is required to assess standards based on a number of statutory factors, including the economic impact of the standard on manufacturers and consumers, as well as ''the utility or performance of the covered product.'' Americans for Tax Reform asserted that the August 2021 NOPR failed to appropriately assess these factors, as the evidence demonstrates faster classes of consumer appliances are of significant benefit to members of the public. Specifically, Americans for Tax Reform referenced polling data that shows in excess of 80 percent of consumers would find such projects useful. Americans for Tax Reform commented that 98 percent of individuals who submitted comments in response to the dishwasher short-cycle product class rulemaking were in favor of the dishwasher short-cycle product class. (Americans for Tax Reform, No. 223 at p. 1) Americans For Tax Reform commented that consumer appliances with shorter cycle times would be particularly beneficial to larger families and cited a 2017 survey from Statista.com that showed that families in lower income brackets tend to have higher birth rates. Americans for Tax Reform suggested that denying access to

[8] *www.regulations.gov/comment/EERE-2017-BT-STD-0014-0019.*

[9] *www.regulations.gov/comment/EERE-2018-BT-STD-0005-2233.*

[10] Dishwasher NODA Test Data (5–21–20). Available at: *www.regulations.gov/document/EERE-2018-BT-STD-0005-3213.*

[11] DOE's Compliance Certification Management System database is available at *www.regulations.doe.gov/certification-data.*

[12] *www.regulations.gov/comment/EERE-2020-BT-STD-0001-0033.*

appliances with shorter cycle times indirectly penalizes low-income families and exacerbates the problems associated with income inequality, asserting that higher-income families or those able to afford housekeeping services may not need shorter cycle times. (Americans for Tax Reform, No. 223 at p. 1) The 60 Plus Association claimed that senior citizens would benefit from cycle times less than an hour. (60 Plus Association, No. 251 at p. 3)

The Arizona AG argued that the August 2021 NOPR, if finalized, would be a detriment to consumers, who stand to benefit greatly from products produced under the new classes of machines and who expressed much support for the two rules. (Arizona AG, No. 248 at p. 1) The Arizona AG highlighted comments from consumers and industry groups about the prior standards, which stated that the prior standards led to machines that did not clean as well and took longer to do it, which created a burden on many, including large families, work professionals, and seniors. (Arizona AG, No. 248 at p. 2)

FreedomWorks Foundation argued that the 2020 Final Rules determined that a new class of dishwashers was a performance-related feature that justified creation of a standard that allowed use of more energy and water. FreedomWorks Foundation claimed that short-cycle product classes would help busy Americans maintain their households, and that repealing these product classes would be neglectful to those citizens. (FreedomWorks Foundation, No. 238 at p. 2) FreedomWorks Foundation and the Arizona AG highlighted consumer comments filed in support of the 2020 Final Rules. (FreedomWorks Foundation, No. 238 at pp. 1–2; Arizona AG, No. 248 at p. 2) The Arizona AG stated that utility to the consumer had been well established by the DOE's previous findings and the hundreds of comments in support in the docket for the 2020 Final Rules. (Arizona AG, No. 248 at pp. 4–5)

CEI argued that these faster products provide substantial utility to consumers. CEI highlighted the magnitude of comments from individual consumers in the prior rulemaking that stated that faster dishwashers would be useful to them. (CEI, No. 239 at p. 2; see also CEI, Public Meeting Transcript, No. 12 at pp. 6–7) CEI commented that more than 2,200 individuals submitted comments supporting the dishwasher short-cycle product class in the rulemaking leading to the October 2020 Final Rule, while only 57 individuals opposed the short-cycle product class or were neutral. (CEI, No. 239 at p. 2) CEI also noted a comment received as a part of this rulemaking, where the commenter stated that ''a short normal cycle clothes washer is essential to someone like me, a working mother doing laundry for a family of six, to allow me to schedule around the sun and use a clothesline rather than being forced into using a heated tumble clothes drier [*sic*].'' (CEI, No. 239 at p. 3) CEI further commissioned a survey of over 1,000 random Americans, of which 81 percent said the new class of short-cycle dishwashers would be useful to them and only 8 percent thought a dishwasher should take more than an hour. (CEI, No. 239 at p. 3; see also CEI, Public Meeting Transcript, No. 12 at pp. 7–8) In further support of its view that short-cycles provide consumer utility, CEI referenced a comment provided by Robert C. Hoffman in response to DOE's July 2019 NOPR to establish the new dishwasher product class, noting that he is an ''expert with nearly three decades of experience in the appliance industry and in DOE compliance testing.'' Hoffman stated that, ''clearly a percentage of the dishwasher market in the U.S. is dissatisfied with current dishwasher cleaning and cycle time performances,'' and viewed DOE's stringent energy standards as restricting the availability of products that were on the market.[13] (CEI, No. 239 at p. 3)

CEI stated that the provision at 42 U.S.C. 6295(q)(1) explicitly allows the establishment of a lower standard for products that have a capacity or other performance-related feature than applies to other products that do not have that feature. (CEI, No. 239 at p. 6) The Arizona AG stated that DOE has the regulatory authority to empower consumers to buy residential dishwashers, residential clothes washers, and consumer clothes dryers that will fit their specific needs and time constraints. The Arizona AG and Missouri AG argued that EPCA authorizes the creation of a ''higher or lower'' energy conservation standard for a new class of products provided that DOE determines that the class is characterized by a distinct performance-related feature. (Arizona AG, No. 248 at p. 4 (citing 42 U.S.C. 6295(q)(1)); Missouri AG, No. 246 at pp. 4–5) Furthermore, the Missouri AG asserted if the current classes of regulated appliances do not accurately describe a new type of product to be introduced to the market, regulators are free to craft a completely new, less burdensome, regulatory scheme for this new product, which is what the 2020 Final Rules did. (Missouri AG. No. 246 at p. 5)

Although irrelevant to the conclusion that the 2020 Final Rules failed to follow the statutory requirements for amending standards, it nonetheless bears mentioning that DOE standards apply only to the particular cycles required by the test procedure for testing these products. Most basic models of residential dishwashers, residential clothes washers, and consumer clothes dryers provide multiple cycle options that are not regulated, each of which are designed for different purposes. For instance, a residential dishwasher may have a quick cycle, heavy cycle, delicates, *etc.* in addition to the normal cycle. These unregulated cycles provide consumers options to their individual needs in the moment. The standards in place prior to the 2020 Final Rules, to which DOE is now reverting, do not impede the inclusion of these cycle options in products currently available on the market.

Further, DOE is not contending in this rulemaking the validity of the determinations made about whether short cycles provide a ''performance-related feature'' and ''utility.'' However, the appropriate occasion for conducting the 42 U.S.C. 6295(q) analysis is in a rulemaking prescribing new or amended standards. As discussed previously, the 2020 Final Rules failed to undertake consideration of the statutory criteria explicitly applicable to a rulemaking to establish a new or amended standard. *See generally* 42 U.S.C. 6295(o). By failing to adhere to the process set out in EPCA for it to consider these prescribed criteria, DOE has concluded that the 2020 Final Rules were promulgated in violation of that process.

4. Other Statutory Concerns

IPI stated that when agencies deregulate in ways that impose costs—including harms to human health and the environment—the Administrative Procedure Act, principles for rational rulemaking, and court precedent all require agencies to consider the forgone benefits of deregulation.[14] IPI commented that the 2020 Final Rules explicitly declined to consider any forgone benefits from those actions. Further, IPI stated that the 2020 Final Rules directly opened the possibility that products could be sold that would

[13] Attachment C: Hoffman Evaluation available at: *www.regulations.gov/comment/EERE-2021-BT-STD-0002-0239.*

[14] *See* Bethany A. Davis Noll & Denise A. Grab, *Deregulation: Process and Procedures that Govern Agency Decisionmaking in an Era of Rollbacks,* 38 ENERGY L. J. 269, 292–93 (2017) (summarizing the legal requirements and case law).

consume unlimited amounts of energy or water could pose the risk of increased consumer costs and pollution, resulting in financial, health, climate, and other environmental harms. IPI asserted that DOE should cite the failure to consider forgone benefits as another justification for revoking the 2020 Final Rules. (IPI, No. 244 at pp. 1–2)

As discussed previously, due to the uncertainty in the market about these product classes and energy conservation standards, it is DOE's understanding that new products in these short-cycle product classes have not entered the market at this time. As such, DOE believes that it is unlikely that the foregone benefits referenced by IPI have resulted.

CEI stated when it made the request for a new product class for dishwashers, it expected DOE to issue the new standard as part of the same rulemaking process that established the new class of product. CEI commented that, instead, DOE decided to split the creation of the standard for this new product class into two different parts, and if DOE now believes that this product class had to be issued with a new standard in one step, as CEI originally requested, then DOE can fix that problem by issuing that standard now. (CEI, No. 239 at p. 7 ; see also CEI, Public Meeting Transcript, No. 12 at p. 8) CEI asserted that other than the absurd idea that DOE cannot create a new product class with a lower energy standard due to a performance-related feature, ''there is no argument that DOE does not have the power to issue a valid standard for these new product classes now.'' Further, CEI argued that issuing a standard for these products is a reasonable regulatory alternative, which the APA requires DOE to consider prior to revoking these product classes. (CEI, No. 239 at p. 7 (citing *California* v. *Interior,* 381 F. Supp. 3d 1153, 1168 (N.D. Cal. 2019) (''When considering revoking a rule, an agency must consider alternatives in lieu of a complete repeal, such as by addressing the deficiencies individually.''); citing *Yakima Valley Cablevision* v. *F.C.C.,* 794 F.2d 737, 746 n. 36 (''The failure of an agency to consider obvious alternative has led uniformly to reversal.'')) Sabedra also suggested that the short-cycle product classes be subject to energy conservation standards, which would ensure companies will continue to move forward with technological advancements that can conserve both water and energy, while filling the market gap that exists for these products. (Sabedra, No. 7) An anonymous commenter also suggested that short-cycle product classes should have regulations for water and cleaning efficiency set for them, so that manufacturers of these products can add this option to their products. (Anonymous, No. 8)

While DOE could propose new standards for short-cycle products—as certain commenters suggested—DOE is declining to do so at this time. DOE reached this judgment after considering: (1) The time and resources that it would entail to develop these new standards in relation to other obligations of the program, (2) the lack of presently-available data that would be necessary to analyze the short-cycle product classes and establish new standards for these class, and (3) the absence of new products on the market that would fall within these new product classes. DOE weighed these factors against the benefit of more quickly fixing an EPCA procedural error through the revocation of this rulemaking. As such, DOE determined that revoking the 2020 Final Rules was the best course of action.

Additionally, as discussed throughout this document, many residential dishwashers, residential clothes washers, and consumer clothes dryers offer shorter cycle options on models already available to consumers. The inclusion of these cycle options has not been hindered by the existing conservation standards, meaning consumers can purchase such models if desired.

Americans for Tax Reform commented that the August 2021 NOPR should be withdrawn because DOE had failed to fulfill the statutory requirements of EPCA by neglecting to complete a cost benefit analysis, an adequate analysis of consumer welfare or the disproportionate harm this rule would cause low-income earners, and a genuine analysis of the environmental impact. (Americans for Tax Reform, No. 223, at p. 2) CEI claimed that repealing the short-cycle product classes would be contrary to the provision at 42 U.S.C. 6295(o)(4), which prohibits DOE from creating standards that eliminate existing ''performance characteristics (including reliability), features, sizes, capacities, and volumes.'' CEI stated that before these new classes of faster products were established, the regulations at issue prevented people from making the trade-off between speed and efficiency. (CEI, No. 239 at p. 1)

As DOE is not establishing or amending energy conservation standards in this final rule under 42 U.S.C. 6295, DOE disagrees with the Americans for Tax Reform that DOE is required to fulfill EPCA's requirements for developing standards when revoking the 2020 Final Rules. Instead, DOE notes that it should have completed such an analysis in the 2020 Final Rules that established the product classes at issue here as discussed in section III.A.1 of this document. Additionally, the revocation of the 2020 Final Rules will return the applicable regulations and the marketplace to the status-quo prior to October 2020. As discussed in section III.A.3 of this document, the marketplace already includes products that provide consumers with shorter cycle options, such as residential dishwasher products with cycles times of less than 60 minutes. As such, the revocation of the 2020 Final Rules will not result in the elimination of any existing performance characteristics from the market.

B. Impact on Water and Energy Use

In the August 2021 NOPR, DOE explained that it made a policy judgment that EPCA's express purpose of energy and water conservation (42 U.S.C. 6201(4), (5), (8)) would be thwarted if DOE could avoid restrictions on amending existing standards by nominally characterizing a regulatory change in the energy conservation standards applicable to a covered product as something other than an amendment. 86 FR 43980, 43974. In response, DOE received comments on the impacts of the proposal on water and energy use. AWE stated that reverting to the prior standards will have significant environmental benefits. Specifically, AWE highlighted that efficient residential clothes washers have helped reduce water use by an average of 5.4 gallons per person per day—nationwide savings of more than 640 billion gallons a year, the single most effective per-capita water reduction effort in 15 years. For consumer clothes dryers, AWE noted DOE findings that prior standards will, over 30 years, save 0.39 quadrillion British thermal units (''quads'') of energy, reduce electricity generation requirements by nearly 1 gigawatt, and reduce carbon dioxide emissions by about 36 million metric tons. AWE also stated that DOE also determined that the prior standards would result in a cumulative national net present value of total consumer costs and savings from $1.08 billion to $3.01 billion for consumer clothes dryers, and from $13.01 billion to $31.29 billion for residential clothes washers. (AWE, No. 254 at pp. 1–2) AWE also commented that the 2020 Final Rules go against the purpose of EPCA to consistently improve energy and water efficiency over time, and stated that if DOE did not revoke the 2020 Final Rules, long-term

consequences could erase water and energy savings produced by previous efficiency standards. (AWE, No. 254 at p. 2) CEC stated that repealing the 2020 Final Rules would ensure that DOE is properly exercising its authority to prevent excess energy and water consumption and save consumers money, instead of allowing products with short cycle times to consume unlimited amounts of energy and water. (CEC, No. 245 at p. 2) ASAP explained that the short-cycle product classes put at risk huge gains in energy and water efficiency that have been achieved in the past three decades for these products. (ASAP, Public Meeting Transcript, No. 12 at pp. 11–12)

NWPCC commented that if the short-cycle product classes remain in effect, machines with primarily short-cycle operations would be developed and would require more per-cycle energy and water use. This could lead to significant energy and water use increases, which would represent backsliding relative to current per-unit consumption rates. NWPCC also noted that clothes washing and drying represents approximately 10 percent of the residential energy load in the northwest region of the United States. (NWPCC, No. 9 at p. 2) NWPCC asserted that while it is unknown how many clothing loads would be performed by short-cycle units in the future, it is clear that the short-cycle product classes would result in an increase in energy and water consumption. (NWPCC, No. 9 at p. 2)

AWE commented that much of the western United States is in an extended drought, and scientists warn that water shortages are likely to become more common and significant due to climate change across the United States because of climate change. (AWE, No. 254 at p. 2) CEC commented that because climate change is threatening communities across the country and the Western United States is experiencing severe drought conditions, with California experiencing extreme or exceptional drought conditions, DOE must utilize every available tool to address climate change and drought. (CEC, No. 245 at p. 2)

The FreedomWorks Foundation claimed that pre-2020 energy and water standards are responsible for increased cycle times and poor residential dishwasher performance that result in consumers frequently hand washing dishes or resorting to other methods that consume additional energy and water. (FreedomWorks Foundation, No. 238 at p. 1) The Arizona AG commented that, during previous rulemakings, consumers expressed concerns about the negative environmental impact of residential dishwashers that must have cycles repeated or extra pre-washing conducted before use. (Arizona AG, No. 248 at p. 3)

Americans for Tax Reform argued that the August 2021 NOPR follows an extremely superficial analysis of the environmental impact, neglecting to consider the abundance of evidence regarding the longer-term environmental benefits brought about through these new classes of products. Americans for Tax Reform suggested that other existing metrics fail to adequately capture the full energy and water use as according to survey data up to 86 percent of Americans wash their dishes by hand at least some or all of the time because of long cycle times. (Americans for Tax Reform, No. 223 at p. 1) Americans for Tax Reform further stated that washing dishes by hand is significantly more water and energy intensive than any form of dishwasher use and, as such, the August 2021 NOPR may significantly increase water usage. Americans for Tax Reform also suggested that longer cycles for residential clothes washers make it more difficult for consumers to time their clothes washing around the weather, so as to take advantage of sunshine to dry their clothes. This could lead to increased energy use as people are forced to use tumble dryers when the new rules would allow for greater use of clotheslines. (Americans for Tax Reform, No. 223 at p. 1) Similarly, Randtke discussed the importance of having a residential clothes washer with a short normal wash cycle time because it allows them to run the clothes washer before work and use a clothesline to dry their families' clothes instead of using a clothes dryer. (Randtke, No. 6 at pp. 1–2) Randtke suggested that longer cycles times for residential clothes washers put pressure on them to switch from a clothesline to a heated tumble clothes dryer, which they asserted uses a lot more energy. (Randtke, No. 6 at p. 3) Randtke also commented that water is necessary to wash clothes, and that to limit water use results in them running multiple cycles for the same load of laundry, as it affects the ability of the washer to get clothes clean. (Randtke, No. 6 at pp. 3–6)

CEI stated that the issue DOE failed to consider is that faster residential dishwashers save water and energy. CEI asserted that even if faster residential dishwashers use more water and energy per cycle, they can still end up saving water and energy by reducing the need for hand washing or extensive pre-scrubbing or running double cycles in order to get dishes clean. (CEI, No. 239 at p. 4) CEI cited its own survey, which showed that 23 percent of consumers always wash their dishes by hand because their residential dishwasher takes too long, 27 percent of consumers do so often, and 37 percent of consumers do so sometimes.[15] (CEI, No. 239 at p. 4; see also CEI, Public Meeting Transcript, No. 12 at p. 8)

Thompson stated that returning to the prior standards will not save energy or water, as people are forced to perform significant pre-rinsing and run multiple loads. Thompson further noted that these efficiency rules that are meant to save energy and water have added to their home's energy and water use, as well as increased the amount of chemicals consumed, and added to the environment [*sic*] through additional detergent and rinse aid use. (Thompson, No. 122) Simpson stated that water and electricity conservation was not needed because an industrialized society can produce more of those things. (Simpson, No. 130)

As stated previously, DOE has determined that the 2020 Final Rules that established the short-cycle product classes and amended the associated energy conservation standards violated EPCA and are, therefore, invalid. The product class structure and associated energy conservation standards that were in effect prior to the 2020 Final Rules, and which DOE is reinstating, were subject to the necessary considerations of energy and water savings, technological feasibility, and economic justification as required by EPCA. *See* 77 FR 31918 (May 30, 2012) (establishing amended energy conservation standards for residential dishwashers); 77 FR 59719 (Oct. 1, 2012) (establishing amended energy conservation standards for residential clothes washers); and 76 FR 22454 (Apr. 21, 2011) (establishing amended energy conservation standards for consumer clothes dryers).

DOE recognizes the concerns raised by commenters about the potential impacts on energy and water use that could result from permitting the 2020 Final Rules to remain in effect. As stated in the August 2021 NOPR, DOE has made a policy judgement that EPCA's expressed purposes for energy and water conservation (42 U.S.C. 6201(4), (5), and (8)) would be thwarted if DOE could avoid EPCA's restrictions on amending existing standards by nominally characterizing a regulatory change to an existing standard as something other than an amendment. 86 FR 43970, 43974. Considerations

[15] Attachment B: Survey Concerning Dishwashers available at: *www.regulations.gov/comment/EERE-2021-BT-STD-0002-0239.*

regarding energy and water use, as well as EPCA's other requirements, should have been addressed during the rulemaking process for the 2020 Final Rules, as discussed in section III.A.1 of this document.

C. Impact to Manufacturers

Commenters also discussed the impact of the proposal on manufacturers. AHAM commented that short-cycle product classes for residential clothes washers and consumer clothes dryers would likely have negative, unintended consequences. Specifically, AHAM stated that retaining the short-cycle product classes could strand manufacturer investments in efficiency and require new investments to develop new products; create new regulation; introduce uncertainty for manufacturers until DOE develops energy conservation standards for the new product classes; increase test burden for laundry products; and create possible disharmony in North American laundry energy conservation standards. (AHAM, No. 253 at p. 3)

GEA commented that by failing to follow the requirements of EPCA, the Appliance Standards Process Rule (*see* 10 CFR part 430, subpart C, appendix A—Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment), and the APA, the 2020 Final Rules damaged the relationship between major appliance manufacturers and DOE, threatened domestic manufacturing of major appliances, and undercut the significant work DOE and manufacturers have done to bring highly effective and efficient appliances to U.S. consumers. According to GEA, manufacturers were unable to plan for and implement any changes in response to the short-cycle product class rulemaking due to the uncertainty created by not establishing standards for the new product classes. GEA stated that manufacturers rely on DOE to consistently follow EPCA and the APA in order to invest with confidence in U.S.-based technology, manufacturing facilities, and jobs because domestic manufacturing requires greater capital investment, longer lead times, and greater risk than sourcing or foreign manufacturing. GEA also noted that manufacturers rely on the information and understanding provided by the standards rulemaking process to make predictions and projections about forthcoming standards and the 3–5-year implementation times for new standards to redesign their products and implement new manufacturing capabilities. (GEA, No. 255 at p. 2)

GEA further noted that the short-cycle product classes could lead to possible job losses, decreased sales, and a loss of confidence in residential dishwashers, residential clothes washers, and consumer clothes dryers. It added that the short-cycle product class rulemaking threatens established manufacturing jobs in the U.S. because the short-cycle product classes are susceptible to being filled with low-quality imported products made by manufacturers that GEA asserts lack the care or resources for consumers, competitors, and DOE to be assured they comply with U.S. law. (GEA, No. 255 at pp. 2–3) GEA commented that the predictability and consistency inherent to the DOE Appliance Standards Program reduce development cost, manufacturing cost, and stranded investment. GEA further explained that all of these cost factors are used to determine what maximum efficiency levels are economically justified for both manufacturers and consumers under EPCA's economic justification requirements. GEA stated, therefore, that the short-cycle product class rulemakings and their impacts on the market threaten to drive up cost for manufacturers and consumers, which would make more efficient products unavailable under EPCA's requirements. GEA added that EPCA's processes are essential to the success of EPCA's ultimate goal of conserving water and energy consumption, and in order to continue to reach for this goal, the short-cycle product classes should be terminated. (GEA, No. 255 at p. 3)

AWE noted that the residential clothes washer and consumer clothes dryer standards preceding the short-cycle rulemaking benefited manufacturers by creating a level, well-understood playing field for American companies that have invested heavily in creating products that meet the prior standards and that reverting to the prior standards will result in essential savings for both consumers and manufacturers. (AWE, No. 254 at p. 2)

CEI countered AHAM and manufacturers' opposition to the formation of short-cycle product classes, stating that the manufacturers' arguments—that there is no utility for the short-cycle product classes, and that their past investment in more efficient products might be wasted—are contradictory because, according to CEI, if no consumers purchase products with shorter cycle times due to a lack of utility, then AHAM members could continue selling higher efficiency products without losing market share and without loss of investment. CEI asserted that some of AHAM's members understand that there is utility to short-cycle products, citing a statement from one AHAM member's senior manager that the manufacturer would probably redesign residential dishwashers if a standard was issued for these products.[16] CEI asserted that short-cycle products are not currently available because DOE has not yet issued a standard for these product classes, and, according to CEI, manufacturers do not want to create products that could soon be illegal to sell if they do not meet that standard. (CEI, No. 239 at p. 3) Americans for Tax Reform also asserted that the lack of new products being introduced to the market is partially attributed to regulatory uncertainty, and argued that this rule would block innovation without assessing future technological innovation. Americans for Tax Reform suggested that, while it is true that no products under the new rules have been presently introduced to the market, that is not an adequate reason to finalize this withdrawal rulemaking. Americans for Tax Reform cautioned DOE against engaging in anti-competitive regulatory policy, which would benefit existing manufacturers, at the expense of newer ones trying to enter the market, and stated that benefiting vested interest to prevent consumer interest would be contrary to sound public policy. (Americans for Tax Reform, No. 223 at p. 2)

The Arizona AG commented that repealing the short-cycle product class would limit consumers' choices and block innovation of technology and products in the marketplace that can meet consumer demands. The Arizona AG added that the technology exists for more helpful machines that meet the needs of modern lifestyles, and that DOE should allow the 2020 short-cycle rulemakings to stand instead of repealing them. (Arizona AG, No. 248 at pp. 5–6)

As discussed in section III.A.1 of this document, in amending the standards for the short-cycle products, DOE failed to consider the potential impacts on manufacturers. Commenters suggest that the standards as amended by the 2020 Final Rules may have economic impacts on manufacturers that were not appropriately considered. Appropriate consideration of the potential impacts on manufacturers resulting from amended product classes would occur

[16] Liam McCabe, Did Trump Really Make Dishwashers Great Again?, New York Times (Mar. 2, 2021). *www.nytimes.com/wirecutter/blog/dishwashers-trump-efficiency/.*

as part of a standards rulemaking as required by EPCA.

D. Other Concerns

The CA IOUs commented that the 2020 Final Rules delayed the EPCA 6- and 7-year lookback periods for energy conservation standards and test procedures, respectively, for dishwashers, clothes washers, and clothes dryers, and created uncertainty in their evaluations. The CA IOUs commented that there is an opportunity to save a significant amount of energy, but the creation of the short-cycle product classes without a testing method to verify product class eligibility or associated energy and water efficiency standards created uncertainty for stakeholders. (CA IOUs, No. 247 at pp. 2–3)

DOE is actively pursuing a robust rulemaking schedule to meet EPCA's 6- and 7- year lookback period requirements for energy conservations standards and test procedures. *See* notice of proposed rulemaking for the residential and commercial clothes washer test procedure (86 FR 49140 (Sept. 1, 2021)); notice and request for comment on a preliminary analysis of residential clothes washer energy conservation standards (86 FR 53886 (Sept. 29, 2021)); notice and request for comment on a preliminary analysis of consumer clothes dryer standards (86 FR 20327 (Apr. 19, 2021)). DOE notes that the requirements regarding the measurement and reporting of cycle-time would more appropriately be addressed in a test procedure rulemaking and DOE therefore is not addressing such requirements in this final rule.

The Joint State AGs, DC, and NYC expressed concern that the 2020 Final Rules have weakened the energy efficiency program by removing standards for important consumer products and creating unjustified product classes, which in turn opened the possibility of similar proposals in the future that could further undermine the program. (Joint State AGs, DC, and NYC, No. 249 at p. 2)

As mentioned in section III.B of this document, DOE recognizes that EPCA's expressed purposes for energy and water conservation would be thwarted if the 2020 Final Rules remained in place, as those rules avoided EPCA's restrictions on amending existing standards to permit the short-cycle products to operate with unlimited energy and water use. By finalizing this proposal, DOE will revoke the 2020 Final Rules and ensure that the energy efficiency program fulfills EPCA's purposes.

IV. Conclusion

After careful consideration, DOE is revoking the October 2020 and December 2020 Final Rules that improperly amended standards and is reinstating the prior product classes and applicable standards for residential dishwashers, residential clothes washers, and consumer clothes dryers. The short-cycle residential dishwashers, residential clothes washers, and consumer clothes dryers were all subject to energy conservation standards prior to the 2020 Final Rules. By stating that short-cycle products were no longer subject to energy or water conservation standards, the 2020 Final Rules allowed for unlimited energy and water use by these short-cycle products. DOE was required to satisfy the requirements in EPCA before issuing these amended standards.

In addition, DOE has made a policy judgment that EPCA's express purposes of energy and water conservation (42 U.S.C. 6201(4), (5), (8)) would be thwarted if DOE could avoid restrictions on amending existing standards by nominally characterizing a regulatory change in the energy conservation standards applicable to a covered product as something other than an amendment. The 2020 Final Rules contravened EPCA by failing to consider these criteria when the rules amended the existing standards for short-cycle products in the 2020 Final Rules.

DOE is not aware of any residential dishwashers, residential clothes washers, or consumer clothes dryers that are certified and sold as short-cycle products at this time. DOE considers the lack of products on the market classified under the short-cycle product definitions and the short time period between 2020 Final Rules and the proposed revocation of those rules by the August 2021 NOPR to indicate a lack of reliance by stakeholders on the short-cycle product class definitions revoked in this final rule.

V. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866

The Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has waived review of this rule pursuant to Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review.''

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*www.energy.gov/gc/office-general-counsel*).

DOE reviewed this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. As discussed, DOE has concluded that this rule would not have a significant impact on a substantial number of small entities. The factual basis for this certification is as follows:

The Small Business Administration (''SBA'') considers a business entity to be a small business, if, together with its affiliates, it employs less than a threshold number of workers or earns less than the average annual receipts specified in 13 CFR part 121. The threshold values set forth in these regulations use size standards and codes established by the North American Industry Classification System (''NAICS'') that are available at: *www.sba.gov/document/support-table-size-standards.* The threshold number for NAICS classification code 335220, ''Major Household Appliance Manufacturing,'' which includes residential dishwasher, residential clothes washer, and consumer clothes dryer manufacturers, is 1,500 employees.

Most of the companies that manufacture residential dishwashers, residential clothes washers, and/or consumer clothes dryers are large multinational corporations. DOE collected data from CCMS [17] and reviewed data from prior rulemakings to identify original equipment manufacturers (''OEMs'') of the products covered by this rulemaking. DOE then consulted publicly available data, such as individual company websites, and subscription-based market research

[17] DOE's Compliance Certification Management System database is available at *www.regulations.doe.gov/certification-data/.*

tools, such as Dun & Bradstreet,[18] to determine whether they meet the SBA's definition of a ''small business manufacturer''. DOE screened out companies that do not offer products covered by this rulemaking, do not meet the definition of a ''small business,'' or are foreign-owned and operated.

In response to the August 2021 NOPR, the 60 Plus Association stated that it observed the agency justification for OMB control number 1910–1400 indicates small businesses are impacted by the collection of information and its associated standards. The 60 Plus Association explained that the August 2021 NOPR indicated that the Regulatory Flexibility Act is not triggered and suggested that DOE review this determination. (60 Plus Association, No. 251 at p. 3)

In the August 2021 NOPR, DOE initially identified two small domestic OEMs of residential dishwashers and zero small domestic OEMs of residential clothes washers or consumer clothes dryers. DOE also initially determined that there were no compliance or other requirements imposed by the proposed rule on manufacturers, including small businesses. 86 FR 43970, 43974–43975. Upon further review, DOE has amended its small business counts for the products covered under this rulemaking. DOE determined that no small domestic OEMs manufacture residential dishwashers or consumer clothes dryers. DOE confirmed that one small domestic OEM manufactures residential clothes washers.

This rulemaking eliminates the product classes for residential clothes washers based on cycle time established in the December 2020 Final Rule. DOE has determined that this final rule would not impose any compliance or other requirements on manufacturers of residential clothes washers, including small businesses, as revoking the December 2020 Final Rule would not eliminate any products on the market.

As a result, DOE certifies that this final rule will not have a significant impact on a substantial number of small entities. Accordingly, DOE has not prepared a FRFA for this rule. DOE has transmitted the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of covered products/equipment, such as residential dishwashers, residential clothes washers, and consumer clothes dryers, must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for residential dishwashers, residential clothes washers, and consumer clothes dryers, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including residential dishwashers, residential clothes washers, and consumer clothes dryers. 76 FR 12422 (Mar. 7, 2011); 80 FR 5099 (Jan. 30, 2015). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The 60 Plus Association commented that the August 2021 NOPR did not clarify whether the collection of information for reporting, recordkeeping, or certification requirements obtained necessary OMB approval, as is required by the Paperwork Reduction Act and the corresponding implementing rule. The 60 Plus Association further stated that the OMB approval of 1910–1400 control number operated illegally for a six month period until approval in September 2021, which indicates that what DOE refers to as a necessary approved collection of information received approval just recently. (60 Plus Association, No. 251, p. 2)

DOE notes that the currently approved information collection request that includes consumer dishwashers, residential clothes washers, and consumer clothes dryers (OMB No. 1910–1400) accounts for the certification of these products without regard to cycle-time distinctions and, therefore, reflects the certification of the products previously defined as short-cycle products.[19]

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

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act of 1969 (''NEPA'') of 1969, DOE has analyzed this proposed action rule in accordance with NEPA and DOE's NEPA implementing regulations (10 CFR part 1021). DOE has determined that this rule qualifies for categorical exclusion under 10 CFR part 1021, subpart D, appendix A5 because it is an interpretive rulemaking that does not change the environmental effect of the rule and meets the requirements for application of a CX. See 10 CFR 1021.410. Therefore, DOE has determined that promulgation of this rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA, and does not require an EA or EIS.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this final rule and has determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for

[18] The Dun & Bradstreet Hoovers subscription login is available at *https://app.dnbhoovers.com/*.

[19] *See* Supporting Statement for Certification Reports, Compliance Statements, Application for a Test Procedure Waiver, and Recording keeping for Consumer Products and Commercial Equipment Subject to Energy or Water Conservation Standards, available at *www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202102-1910-002*.

the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Section 3(a), section 3(b) of E.O. 12988 specifically requires that executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, section 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *https://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.*

DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate nor a mandate that may result in the expenditures of $100 million or more in any one year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 15, 1988), DOE has determined that this regulation will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the regulation be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action, which would eliminate certain product classes for residential dishwashers, residential clothes washers, and consumer clothes dryers would not have a significant adverse effect on the supply, distribution, or use of energy and, therefore, is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects on this final rule.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on January 11, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 12, 2022.

Treena V. Garrett,

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

For the reasons set forth in the preamble, DOE amends part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, to read as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.32 is amended by:
■ a. Removing paragraph (f)(1)(iii); and
■ b. Revising paragraphs (g)(4) and (h)(3).

The revisions read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(g) * * *

(4) Clothes washers manufactured on or after January 1, 2018, shall have an Integrated Modified Energy Factor no less than, and an Integrated Water Factor no greater than:

Product class	Integrated modified energy factor (cu.ft./kWh/cycle)	Integrated water factor (gal/cycle/cu.ft.)
(i) Top-loading, Compact (less than 1.6 ft^3 capacity)	1.15	12.0
(ii) Top-loading, Standard (1.6 ft^3 or greater capacity)	1.57	6.5
(iii) Front-loading, Compact (less than 1.6 ft^3 capacity)	1.13	8.3
(iv) Front-loading, Standard (1.6 ft^3 or greater capacity)	1.84	4.7

(h) * * *

(3) Clothes dryers manufactured on or after January 1, 2015, shall have a combined energy factor no less than:

Product class	Combined energy factor (lbs/kWh)
(i) Vented Electric, Standard (4.4 ft^3 or greater capacity)	3.73
(ii) Vented Electric, Compact (120V) (less than 4.4 ft^3 capacity)	3.61
(iii) Vented Electric, Compact (240V) (less than 4.4 ft^3 capacity)	3.27
(iv) Vented Gas	3.30
(v) Ventless Electric, Compact (240V) (less than 4.4 ft^3 capacity)	2.55
(vi) Ventless Electric, Combination Washer-Dryer	2.08

* * * * *

[FR Doc. 2022–00833 Filed 1–18–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. FAA–2021–0065; Special Conditions No. 29–054–SC]

Special Conditions: Bell Textron Inc. Model 525 Helicopter; Fly-By-Wire Flight Control System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Bell Textron Inc. (Bell) Model 525 helicopter. This helicopter will have a novel or unusual design feature associated with a fly-by-wire (FBW) flight control system (FCS). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Effective February 18, 2022.

FOR FURTHER INFORMATION CONTACT: John VanHoudt, FAA, Dynamic Systems Section, AIR–627, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524; telephone and fax 817–222–5193; email *John.G.Van.Houdt@FAA.Gov*.

SUPPLEMENTARY INFORMATION:

Background

On December 15, 2011, Bell applied for a type certificate for a new transport category helicopter, designated as the Model 525, under Title 14, Code of Federal Regulations (CFR) part 29. Bell applied for multiple extensions, with the most recent occurring on November 12, 2020. The date of the updated type certification basis is December 31, 2016, based upon the applicant's proposed type certificate issuance date of December 31, 2021. The Model 525 is a

medium twin-engine rotorcraft. The design maximum takeoff weight is 20,500 pounds, with a maximum capacity of 19 passengers and a crew of two.

The Bell Model 525 helicopter will be equipped with a four axis full authority digital FBW FCS that provides for aircraft control through pilot input and coupled flight director modes. The design of the Bell Model 525 FBW controls, which provides no direct hydro-mechanical linkage between the primary cockpit flight controls or inceptors and the main and tail rotor actuators, is a first for commercial rotorcraft use. Therefore, the regulations do not contain adequate or appropriate safety standards for this new design feature.

The rotorcraft industry is producing new generations of helicopters, and gradually increasing size, speed, load capacity, and technical sophistication. In recent years, an accelerated trend has occurred using rotorcraft for a wide range of commercial and industrial applications. This has resulted in increased complexity of modern control systems and increased use of automation in flight control systems, including the implementation of advanced flight control systems such as FBW FCS.

Section 29.671(c), which provides requirements for transport category rotorcraft control systems, does not contain adequate or appropriate safety standards for this new design feature. Section 29.671(c) requires, in part, a means to allow the pilot to determine that full control authority is available prior to flight. This command control authority is typically achieved by verifying movement of the control quadrant through an unassisted mechanical pilot-initiated manipulation of the primary flight controls prior to flight. Although this approach does not guarantee that 100% maximum control movement of the flight controls has been achieved prior to flight, it has been deemed appropriate for mechanical flight control systems.

Unlike traditional mechanical flight control systems, the FBW FCS reduces the opportunity for jamming of the flight controls due to mechanical bind, improper servo adjustment resulting from faulty maintenance, or presence of a foreign object in the control mechanism that will impair safety. This reduced exposure for jams is due to the replacement of the mechanical linkages between the primary cockpit flight controls or inceptors and the main and tail rotor actuators with digital signal processing wiring. However, the FBW FCS does increase the potential for latent failures or faults that could impair full control authority, unless a means exists to ensure the FBW FCS is fully functional and free of control authority impairment prior to flight. A FBW system may have the ability to verify full control authority without having to move the primary flight controls.

Although part 29 does not contain adequate or appropriate safety standards for this novel or unusual design feature, 14 CFR 25.671, amendment 25–23, provides these requirements for transport category airplanes. Accordingly, these special conditions are based on § 25.671 to provide requirements for a FBW FCS on the Bell Model 525 helicopter. Section 25.671(c) provides the same level of safety as intended by § 29.671(c) when employing a FBW FCS by including requirements for jamming and failure analysis. These special conditions require a comprehensive safety analysis of the aircraft's FBW FCS to include failures due to command logic (software), mechanical and electronic interfaces to other systems, jamming, and maintenance. Therefore, in conjunction with § 29.671(a) and (b), these special conditions incorporate provisions from § 25.671(c) to establish a level of safety equivalent to that established in the regulations.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Bell must show that the Model 525 helicopter meets the applicable provisions of part 29, as amended by Amendments 29 through 55 thereto. The Bell Model 525 certification basis date is December 31, 2016.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* part 29) do not contain adequate or appropriate safety standards for the Bell Model 525 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Bell Model 525 helicopter must comply with the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Bell Model 525 helicopter will incorporate the following novel or unusual design features: A FBW FCS.

This new design feature has no direct hydro-mechanical linkage between the primary cockpit flight controls or inceptors and the main and tail rotor actuators, thereby eliminating the more complex elements of either a manual movement of the controls by the pilot, or another manual means.

Discussion

These special conditions require that a means be available to show full control authority for all powered control systems.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Discussion of Comments

The FAA issued Notice of Proposed Special Conditions No. 29–054–SC for the Bell Model 525 helicopter, which published in the **Federal Register** on January 29, 2021 (86 FR 7516). The FAA received one response, from the European Union Aviation Safety Agency (EASA).

The FAA proposed the special conditions, which are based on current § 25.671(c), in lieu of § 29.671(c). EASA requested the FAA explain its rationale for replacing § 29.671(c), which requires a means to allow either full movement of all primary flight controls or a determination by the pilot that full control authority is available prior to flight. EASA stated that although FBW reduces the risk of jamming, it does not alleviate the need to allow checking the full control movement prior to flight and thus a pre-flight check is still necessary.

The FAA is not replacing the requirement for a pre-flight check. Instead, these special conditions include a requirement for a comprehensive safety analysis to ensure the FBW FCS is fully functional and free of control authority impairment prior to flight. The comprehensive safety analysis should address failures due to command logic (software), mechanical and electronic interfaces to other systems, jamming, and maintenance. The safety analysis should also identify the existence of any latent faults.

Therefore, the means to ensure the FBW FCS is fully functional and free of control authority impairment prior to flight is based on the results of the comprehensive safety analysis. The means to ensure the safety objective of the special conditions is met may consist of design, analysis, test, built in test, and limited pre-flight checks.

EASA noted the proposed special conditions, although derived from § 25.671(c), are not aligned with EASA's latest Certification Specifications (CS) 25.671 (Amendment 24).

Under § 21.16, special conditions prescribed by the FAA must establish a level of safety equivalent to that established in the FAA's existing regulations. Accordingly, the FAA based these special conditions on 14 CFR 25.671(c) and not on EASA's certification specifications.

EASA requested the FAA clarify its use of the term ''continued safe flight and landing'' used in the proposed special conditions. EASA stated the term has a specific definition for flight control failures on large airplanes and asked whether the FAA will use a consistent definition for failure conditions under § 29.1309. EASA also asked whether the FAA will provide a definition of ''continued safe flight and landing'' in the context of flight control failures.

Advisory Circular 29–2C, *Certification of Transport Category Rotorcraft* (AC 29–2C), contains a definition for ''continued safe flight and landing.'' The FAA plans to use this definition for the purposes of these special conditions.

EASA stated the proposed special conditions introduce the term ''normal flight envelope,'' which is not present in EASA's CS 29 regulation. EASA questioned whether it is relevant only to the Bell Model 525 and whether it means the same as ''operating'' envelope.

When § 25.671 was incorporated, the ''normal flight envelope'' was the aircraft approved operating limitations contained in the aircraft flight manual. This proposed special condition has the same intent. In order to provide clarity and consistency in the language between this special condition and § 29.672, the wording will be revised to approved operating limitations.

EASA asked what the FAA means by the proposed requirement that ''probable failures have only minor effects.'' Specifically, EASA asked whether a probable failure is greater than $1E^{-5}$ per flight hour and whether ''no safety effect'' would be a noncompliance.

In AC 29–2C, the upper part of the range previously applied to the term ''probable'' has been redefined as ''reasonably probable.'' Accordingly, the FAA has revised these special conditions by replacing ''probable'' with ''reasonably probable.'' As provided in AC 29–2C, reasonably probable events are based on a probability on the order of between 10^{-3} to 10^{-5}. If a failure is classified as ''no safety effect,'' then no further showing of compliance would be required.

EASA requested the FAA change the language in paragraphs (1) and (2) of the proposed special conditions to reference failures as defined in § 29.671(c)(3). EASA states its suggested language will avoid a gap between EASA CS 29.671(c)(1) and 29.671(c)(3).

The FAA agrees and made the suggested change in the special conditions.

EASA stated that if the FAA's special conditions have a no single failure criterion under § 29.1309, then jams under § 29.671(c)(3) may need to be excluded. EASA referenced CS 25.1309 (Amendment 24) for no single failure.

EASA is correct; there is no criteria for single failure in § 29.1309. As such, the FAA has removed the ''single'' descriptor from the special conditions language to be consistent with § 29.1309 safety objectives. The FAA does not agree that jams under § 29.671(c)(3) need to be excluded. Any failure condition that can be shown to be extremely improbable isn't limited by failures that occur from a single source.

EASA stated that using language from § 25.671(c), which is applicable to transport category airplanes, is overly ambitious for rotorcraft. EASA asked several hypothetical questions concerning how an applicant would show compliance and requested the FAA provide further guidance.

Section 29.671(c), which these special conditions replace as a certification requirement for the Model 525, requires either a means to allow full control movement of the primary flight controls prior to flight or a means that will allow the pilot to determine that full control authority is available prior to flight. The language utilized from § 25.671(c) for these special conditions ensures verification of the control authority prior to flight via a comprehensive safety analysis. This analysis is necessary to address failures that could not be detected by full control movement of the digital primary flight controls.

EASA requested the FAA clarify whether § 29.691 is sufficient for an FBW system or whether specific guidance is needed for FBW flight controls after a power failure at entry into and during autorotation.

The requirements in § 29.691, and the accompanying guidance in AC 29–2C, are sufficient for an FBW system. Section 29.691 requires that the flight control design allow rapid entry into autorotation after a power failure. AC 29–2C provides that applicants may comply with this rule through an evaluation as part of the Type Inspection Authorization test program.

EASA requested the FAA clarify the meaning of ''normally encountered'' in paragraph (3) of the proposed special conditions. Specifically, EASA asked whether there are jams that are not considered normal and are therefore excluded from the assessment. EASA further noted that the flight conditions listed in paragraph (3) of the proposed special conditions are contrary to the maneuvers required by §§ 29.141 and 29.143.

The FAA intended these special conditions to address jams encountered during any flight condition including transitions between flight conditions. The FAA has revised paragraph (3) accordingly.

EASA requested the FAA clarify the relationship between the proposed special conditions and § 29.685(a), which addresses flight control jamming. EASA noted the approach in § 29.685(a) is different from the one proposed in the special conditions, as § 29.685(a) requires the design of the control system to prevent jamming. EASA states the proposed special conditions would not provide credit for jamming that may result in a condition where continued safe flight is guaranteed.

Section 29.685(a) contains a design requirement for mechanical controls and is limited in scope. These special conditions are broader and include FBW primary flight controls that did not exist when § 29.685 was promulgated in 1964. Regarding EASA's statement about credit, paragraph (3) of these special conditions require reducing jamming in any phase of flight to a level capable of continued safe flight and landing.

Applicability

These special conditions are applicable to the Bell Model 525 helicopter. Should Bell apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on the Bell Model 525 helicopter. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 29

Aircraft, Aviation safety, Reporting, and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Bell Textron Inc. Model 525 helicopter. Unless otherwise stated, the following special conditions will be used in lieu of § 29.671(c).

The rotorcraft must be shown by analysis and tests, to be capable of continued safe flight and landing after any of the following failures or jamming in the flight control system for any speed or altitude within the approved operating limitations, without requiring exceptional piloting skill or strength. Reasonably probable failures must have only minor effects.

(1) Any failure, excluding a jam as listed in paragraph (3).

(2) Any combination of failures not shown to be extremely improbable, excluding a jam as listed in paragraph (3).

(3) Any jam in a control position encountered during any flight condition, including transitions, within the approved operating limitations, unless the jam is shown to be extremely improbable, or can be alleviated.

Issued in Kansas City, Missouri, on January 12, 2022.

Patrick Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–00862 Filed 1–18–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0004; Project Identifier AD–2022–00036–T; Amendment 39–21913; AD 2022–02–16]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a recent determination that, during landings, as a result of this interference, certain airplane systems may not properly transition from AIR to GROUND mode when landing on certain runways, resulting in degraded deceleration performance and longer landing distance than normal due to the effect on thrust reverser deployment, speedbrake deployment, and increased idle thrust. This AD requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate limitations prohibiting certain landings and the use of certain minimum equipment list (MEL) items, and to incorporate operating procedures for calculating landing distances, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 19, 2022.

The FAA must receive comments on this AD by March 7, 2022.

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

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

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0004; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dean Thompson, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3165; email: *dean.r.thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In March 2020, the United States Federal Communications Commission (FCC) adopted final rules authorizing flexible use of the 3.7–3.98 GHz band for next generation services, including 5G and other advanced spectrum-based services.[1] Pursuant to these rules, C-Band wireless broadband deployment is permitted to occur in phases with the opportunity for operations in the lower 0.1 GHz of the band (3.7–3.8 GHz) in certain markets as early as January 19, 2022. This AD refers to ''5G C-Band'' interference, but wireless broadband technologies, other than 5G, may use the same frequency band.[2] These other uses of the same frequency band are within the scope of this AD since they would introduce the same risk of radio altimeter interference as 5G C-Band.

The radio altimeter is an important aircraft instrument, and its intended function is to provide direct height-above-terrain/water information to a variety of aircraft systems. Commercial aviation radio altimeters operate in the 4.2–4.4 GHz band, which is separated by 0.22 GHz from the C-Band telecommunication systems in the 3.7–3.98 GHz band. The radio altimeter is more precise than a barometric altimeter and for that reason is used where aircraft height over the ground needs to be precisely measured, such as autoland, manual landings, or other low altitude operations. The receiver on the radio altimeter is typically highly accurate, however it may deliver erroneous results in the presence of out-of-band radio frequency emissions from other frequency bands. The radio altimeter must detect faint signals reflected off the ground to measure altitude, in a manner similar to radar. Out-of-band signals could significantly degrade radio altimeter functions during critical phases of flight, if the altimeter is unable to sufficiently reject those signals.

[1] The FCC's rules did not make C-Band wireless broadband available in Alaska, Hawaii, and the U.S. Territories.

[2] The regulatory text of the AD uses the term ''5G C-Band'' which, for purposes of this AD, has the same meaning as ''5G'', ''C-Band'' and ''3.7–3.98 GHz.''

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12) to address the effect of 5G C-Band interference on all transport and commuter category airplanes equipped with a radio (also known as radar) altimeter. AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations, which require radio altimeter data to land in low visibility conditions, when in the presence of 5G C-Band interference as identified by NOTAM. The FAA issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.,* landing flare), could lead to loss of continued safe flight and landing.

Since the FAA issued AD 2021–23–12, Boeing issued Boeing Multi Operator Message MOM–MOM–22–0001–01B, dated January 3, 2022, and Boeing Flight Crew Operations Manual Bulletin TBC–119, ''Radio Altimeter Anomalies due to 5G C-Band Wireless Broadband Interference in the United States,'' dated January 5, 2022.

Based on Boeing's data, the FAA identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. The FAA determined anomalies due to 5G C-Band interference may affect multiple other airplane systems using radio altimeter data, regardless of the approach type or weather. These anomalies may not be evident until very low altitudes. Impacted systems include, but are not limited to: Autopilot flight director system; autothrottle system; engines; thrust reversers; flight controls; flight instruments; traffic alert and collision avoidance system (TCAS); ground proximity warning system (GPWS); and configuration warnings.

Many of an airplane's systems and functions are divided into two modes: Those that operate when an airplane is flying (AIR), and those that operate when an airplane is on the ground (GROUND). During landing, this interference could prevent an airplane's systems and functions from properly transitioning from AIR to GROUND mode, which may have multiple effects, including:

- Autothrottle may remain in speed (SPD) mode and may increase thrust to maintain speed during flare instead of reducing the thrust to IDLE at 25 feet radio altitude (RA) or may reduce thrust to IDLE prematurely.
- Thrust reversers may not deploy above 65 knots during the landing roll.
- Engines may remain at approach idle after touchdown until 65 knots during the landing roll.
- Auto Speedbrake may be inoperative during the landing roll.
- SPEEDBRAKE EXTENDED Caution message may not be available during the landing roll.
- SPEEDBRAKE time critical visual and aural warnings may not be available during the landing roll.
- Spoilers may be limited to their maximum in-flight position during manual deployment after touchdown until 65 knots during the landing roll.
- Other simultaneous flight deck effects associated with the 5G C-Band interference could increase pilot workload.

As a result of these effects, lack of thrust reverser and speedbrake deployment and increased idle thrust may occur; and brakes may be the only means to slow the airplane. Therefore, the presence of 5G C-Band interference can result in degraded deceleration performance, increased landing distance, and runway excursion. This is an unsafe condition.

The severity of the hazard created by a lack of thrust reverser and speedbrakes, and by increased idle thrust, increases when the runway is contaminated with frozen or liquid precipitation. The FAA categorizes runway surface conditions with codes from 6 through 0, with 6 being a dry runway and therefore no detrimental effect on braking, and a code of 0 denoting surface conditions, such as wet ice, in which braking may not be effective.

This AD mandates procedures for operators to account for this longer landing distance, for all runway conditions, in the presence of 5G C-Band interference as identified by NOTAM. It prohibits operators from dispatching or releasing airplanes to affected airports when certain braking and anti-skid functions on the airplane are inoperable. It also prohibits operators from dispatching or releasing airplanes to, or landing on, runways with condition codes 1 and 0.

The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires revising the limitations and operating procedures sections of the existing AFM to incorporate limitations prohibiting certain landings and the use of certain MEL items, and to incorporate operating procedures for calculating required landing field lengths, when in the presence of 5G C-Band interference as identified by NOTAMs.

Compliance With AFM Revisions

Section 91.9 prohibits any person from operating a civil aircraft without complying with the operating limitations specified in the AFM. FAA regulations also require operators to furnish pilots with any changes to the AFM (14 CFR 121.137) and pilots in command to be familiar with the AFM (14 CFR 91.505).

Interim Action

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

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because, during landings, as a result of 5G C-Band interference, certain airplane systems may not properly transition from AIR to GROUND mode when landing on certain runways, resulting in degraded deceleration performance and a longer landing distance than normal due to the effect on thrust reverser deployment, speedbrake deployment, and increased idle thrust. This could lead to a runway excursion. The urgency is based on C-Band wireless broadband deployment, which is expected to occur in phases with operations beginning as soon as January 19, 2022. Accordingly, notice and opportunity for prior public comment are impracticable and contrary

to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2022–0004 and Project Identifier AD–2022–00036–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 Dean Thompson, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3165; email: *dean.r.thompson@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

The requirements of the Regulatory Flexibility Act (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 137 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision	1 work-hour × $85 per hour = $85	$0	$85	$11,645

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–02–16 The Boeing Company: Amendment 39–21913; Docket No. FAA–2022–0004; Project Identifier AD–2022–00036–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 19, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8, 787–9, and 787–10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied upon to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that, during landings, as a result of this interference, certain airplane systems may not properly transition from

AIR to GROUND mode when landing on certain runways, resulting in a longer landing distance than normal due to the effect on thrust reverser deployment, speedbrake deployment, and increased idle thrust. The FAA is issuing this AD to address degraded deceleration performance and longer landing distance, which could lead to a runway excursion.

(f) Compliance

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

(g) Definitions

Runway condition codes are defined in figure 1 to paragraph (g) of this AD.

Figure 1 to paragraph (g) – *Runway Condition Codes*

Runway Condition Code	Runway Condition Description	Reported Braking Action
6	Dry	Dry
5	Wet (smooth, grooved, or porous friction course (PFC)) or frost 3 mm (0.12 inches) or less of: water, slush, dry snow, or wet snow	Good
4	Compacted snow at or below -15°C (5°F) outside air temperature (OAT)	Good to medium
3	Wet (slippery), dry snow, or wet snow (any depth) over compacted snow Greater than 3 mm (0.12 inches) of: dry snow or wet snow Compacted snow at OAT warmer than -15°C (5°F)	Medium
2	Greater than 3 mm (0.12 inches) of: water or slush	Medium to poor
1	Ice	Poor
0	Wet ice, water on top of compacted snow, dry snow, or wet snow over ice	Nil

(h) Airplane Flight Manual (AFM) Revision

(1) Within 2 days after the effective date of this AD: Revise the Limitations Section of the existing AFM to include the information specified in figure 2 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 2 to paragraph (h)(1) of this AD into the existing AFM.

Figure 2 to paragraph (h)(1) – *AFM Limitations Revisions*

(Required by AD 2022-02-16)

Radio Altimeter 5G C-Band Interference, Landing Distance

The following limitations are required if dispatching or releasing to or landing on runways in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

Minimum Equipment List (MEL)

Dispatch or release with any of the following MEL items is prohibited:

- 32-42-02 – Antiskid Control Systems
- 32-45-01 – Wheel Brake Systems
- 32-45-01-01 – Wheel Brake Systems, Electric Brake Actuator Systems

Landing Operations on Runways with Condition Code 1 or 0

Dispatch or releasing to or landing on runways with a runway condition code of 1 or 0 is prohibited.

Landing Distance Calculations for Runway Condition Codes 6 through 2

Operators must follow the 5G C-Band Interference Landing Distance Procedure contained in the Operating Procedures Section of this AFM.

(2) Within 2 days after the effective date of this AD: Revise the Operating Procedures Section of the existing AFM to include the information specified in figure 3 to paragraph (h)(2) of this AD. This may be done by inserting a copy of figure 3 to paragraph (h)(2) of this AD into the existing AFM.

Figure 3 to paragraph (h)(2) – *AFM Operating Procedures Revision*

(Required by AD 2022-02-16)

5G C-Band Interference Landing Distance

When dispatching or releasing to or landing on runways with a runway condition code of 6 through 2:

- Dispatch or Release:
  - No additional landing distance calculations are required for runway condition codes 6 and 5.
  - For runway condition codes 4 through 2, use Table 1 through 6, as applicable, to determine the unfactored landing distance, applying all adjustments. Multiply the resulting unfactored landing distance by 1.15 to obtain the minimum required landing distance.

Table 1:

787-10 / TRENT 1000

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	440,000 LB Landing Weight	Per 10,000 LB Above / Below 440,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5640	110 / -90	160	-240 / 790	90 / -80	150 / -150	230	0	0
5	7680	170 / -150	330	-430 / 1570	250 / -210	280 / -270	390	0	0
4	8450	170 / -150	340	-450 / 1610	330 / -270	280 / -280	390	0	0
3	9180	170 / -150	340	-470 / 1680	440 / -340	290 / -280	390	0	0
2	12180	280 / -250	560	-770 / 2850	970 / -690	480 / -460	540	0	0

Table 2:

787-10 / GEnx

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	440,000 LB Landing Weight	Per 10,000 LB Above / Below 440,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5670	110 / -90	170	-240 / 800	90 / -80	150 / -150	230	0	0
5	7760	160 / -150	350	-440 / 1590	260 / -220	280 / -280	400	0	0
4	8550	160 / -150	350	-450 / 1640	340 / -280	290 / -280	400	0	0
3	9300	170 / -150	360	-480 / 1710	450 / -350	290 / -290	400	0	0
2	12400	280 / -250	610	-790 / 2930	1010 / -710	480 / -470	540	0	0

Table 3:

787-9 / TRENT 1000

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	420,000 LB Landing Weight	Per 10,000 LB Above / Below 420,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5470	100 / -90	160	-240 / 780	80 / -80	150 / -150	230	0	0
5	7500	160 / -150	330	-430 / 1550	250 / -210	280 / -270	390	0	0
4	8280	160 / -150	330	-440 / 1600	330 / -270	280 / -270	390	0	0
3	9010	170 / -160	340	-470 / 1670	430 / -340	290 / -280	390	0	0
2	11740	270 / -260	540	-750 / 2780	910 / -650	460 / -440	530	0	0

Table 4:

787-9 / GEnx

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	420,000 LB Landing Weight	Per 10,000 LB Above / Below 420,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5500	100 / -90	170	-240 / 790	90 / -80	150 / -150	230	0	0
5	7580	160 / -150	340	-430 / 1580	250 / -210	280 / -280	390	0	0
4	8380	160 / -150	350	-450 / 1630	340 / -280	280 / -280	390	0	0
3	9130	170 / -150	360	-480 / 1700	450 / -350	290 / -280	390	0	0
2	11960	270 / -260	590	-770 / 2860	940 / -670	460 / -460	530	0	0

Table 5:

787-8 / TRENT 1000

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	380,000 LB Landing Weight	Per 10,000 LB Above / Below 380,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5050	110 / -80	150	-230 / 750	80 / -70	130 / -130	220	0	0
5	6990	180 / -140	310	-410 / 1510	230 / -190	260 / -250	370	0	0
4	7410	140 / -130	250	-370 / 1270	280 / -230	210 / -210	310	0	0
3	8370	170 / -150	290	-440 / 1500	410 / -320	250 / -250	340	0	0
2	10800	290 / -240	520	-720 / 2680	820 / -590	430 / -420	510	0	0

Table 6:

787-8 / GEnx

	Landing Distances and Adjustments (Feet)								
	Reference Distance	Weight Adjustment	Altitude Adjustment	Wind Adjustment per 10 Knots	Slope Adjustment per 1%	Temperature Adjustment per 10°C	Approach Speed Adjustment	Reverse Thrust Adjustment	
Runway Condition Code	380,000 LB Landing Weight	Per 10,000 LB Above / Below 380,000 LB	Per 1,000 ft	Head / Tail Wind	Down / Up Hill	Above / Below ISA	per 5 KTS above VREF	One Reverser	No Reverser
6	5100	110 / -80	160	-230 / 760	80 / -70	130 / -140	220	0	0
5	7100	180 / -140	330	-420 / 1550	240 / -200	260 / -250	380	0	0
4	7530	140 / -120	260	-380 / 1290	290 / -240	210 / -220	310	0	0
3	8530	160 / -140	300	-450 / 1530	430 / -330	250 / -250	340	0	0
2	11090	290 / -240	560	-740 / 2790	880 / -620	430 / -430	510	0	0

Reference distance is based on Max Manual Braking, sea level, standard day, no wind or slope, and no reverse thrust.
Reference distance includes a distance from threshold to touchdown associated with flare time of 7 seconds.
Distances are based on HYD PRESS L+R failure distances which conservatively approximate the effects of 5G interference.
Actual (unfactored) distances are shown.
Note: per procedure, Max Manual Braking is not required for normal operations and is to be used only in the event that significant 5G interference effects occur.

- En route:
  - Plan to use Flaps 30 and V_{REF30} (with appropriate wind additives) for landing.
  - For runway condition codes 6 to 2, compute time of arrival (en route) landing distance using Table 1 through 6, as applicable, applying all adjustments. Multiply the resulting unfactored landing distance by 1.15 to obtain the minimum required landing distance at the destination. This approximates a minimum required landing distance resulting from 5G C-Band interference.
  - Determine desired AUTOBRAKE setting by using the normal configuration landing distance information from an approved source. Maximum manual braking may not be required.

- During approach and landing:
  - Monitor radio altimeter for anomalies.
  - Normal use of autothrottles is allowed. Monitor performance of autopilot and autothrottle. If the autopilot or autothrottle is not performing as expected, disconnect both the autopilot and autothrottle and apply manual inputs to ensure proper control of flight path.
  - If the autothrottle does not reduce the thrust to IDLE at 25 feet, manually reduce the thrust to idle, hold the thrust levers in the idle position and disconnect the autothrottle to prevent autothrottle from advancing the thrust levers after touchdown.
    Caution: If the autothrottle advances the thrust levers after landing, the speedbrakes will stow and the autobrake will disarm. It will not be possible to raise the reverse thrust levers to deploy the thrust reversers until the thrust levers are at idle.
  - Manual deployment of the speedbrakes may be required.
  - If the thrust reversers do not deploy, immediately ensure the speedbrakes are extended, apply manual braking and modulate as required for the existing runway conditions.
    Note: In some conditions, maximum manual braking may be required throughout the entire landing roll.

Note 1 to paragraph (h): Guidance for accomplishing the actions required by this AD can be found in Boeing Multi Operator Message MOM–MOM–22–0001–01B, dated January 3, 2022, and Boeing Flight Crew Operations Manual Bulletin TBC–119, ''Radio Altimeter Anomalies due to 5G C-Band Wireless Broadband Interference in the United States,'' dated January 5, 2022.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the provisions of this AD.

(j) Related Information

(1) For more information about this AD, contact Dean Thompson, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3165; email: *dean.r.thompson@faa.gov*.

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

(k) Material Incorporated by Reference

None.

Issued on January 13, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–01030 Filed 1–14–22; 2:00 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0793; Project Identifier MCAI–2021–00372–E; Amendment 39–21885; AD 2021–26–26]

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 superseding Airworthiness Directive (AD) 2005–12–08 for certain Safran Helicopter Engines, S.A. (Safran Helicopter Engines) Arrius 2B1, 2B1A, 2B1A–1, and 2B2 model turboshaft engines. AD 2005–12–08 required replacing the software in the engine electronic control unit (EECU). This AD was prompted by a report of simultaneous loss of automatic control on both engines installed on an Airbus Helicopters Deutschland (formerly Eurocopter Deutschland) EC135 helicopter during flight. This AD requires replacement of the EECU or upgrade of the EECU software for engines with a certain EECU part number (P/N) installed. This AD also prohibits installation of an affected EECU onto any engine. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 23, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 23, 2022.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of June 29, 2005 (70 FR 34334, June 14, 2005).

ADDRESSES: For service information identified in this final rule, contact Safran Helicopter Engines, S.A., Avenue du 1er Mai, 40220 Tarnos, France; phone: +33 (0) 5 59 74 45 00. You may view this service information at the Airworthiness Products Section,

Operational Safety Branch, FAA, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0793.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0793; 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 Document Operations, 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 to supersede AD 2005–12–08, Amendment 39–14124 (70 FR 34334, June 14, 2005), (AD 2005–12–08). AD 2005–12–08 applied to all Safran Helicopter Engines (Type Certificate previously held by Turbomeca S.A.) Arrius 2 B1, 2 B1A, 2 B1A–1, and 2 B2 model turboshaft engines. These engines are installed on, but not limited to, Eurocopter Deutschland GmbH EC 135T1 and EC 135 T2 helicopters. The NPRM published in the **Federal Register** on September 20, 2021 (86 FR 52106). The NPRM was prompted by a report of simultaneous loss of automatic control on both engines installed on an Airbus Helicopters Deutschland (formerly Eurocopter Deutschland) EC135 helicopter during flight. In addition, the manufacturer more recently determined that certain EECUs identified in AD 2005–12–08 are not subject to the unsafe condition. In the NPRM, the FAA proposed to require replacement of the EECU or upgrade of the EECU software for engines with a certain EECU P/N installed. In the NPRM, the FAA also proposed to prohibit installation of an affected EECU onto any engine. 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 2021–0088, dated March 24, 2021. EASA AD 2021–0088 was revised by EASA AD 2021–0088R1, dated July 26, 2021 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> An occurrence was reported of simultaneous loss of automatic control in flight of both ARRIUS 2B1 engines on an EC135 T1 helicopter. Loss of automatic control would result, for each engine, from a difference between the position datum of the fuel metering valve and its measured position.
>
> This condition, if not corrected, could lead to increased work for flight crew during certain flight phases, possibly resulting in reduced control of the helicopter.
>
> To address this potential unsafe condition, Turbomeca developed mod TU80C, TU81C, TU82C and TU90C to improve the DECU software for ARRIUS 2B1 engines without overspeed option, ARRIUS 2B1 engines with overspeed option, ARRIUS 2B1A and ARRIUS 2B2 engines, and DGAC France issued AD F–2004–017 (later revised) to require engine modification.
>
> Since that [DGAC France] AD was issued, it was determined that a DECU having a P/N which corresponds to Turbomeca mod TU80C, TU81C, TU82C, TU90C or later software is not affected by the software modification requirement. DGAC France AD F–2004–017R1 did not specifically identify any affected DECU P/N(s).
>
> For the reason described above, this [EASA] AD retains the requirements of DGAC France AD F–2004–017R1 (EASA approval 2004–1618), which is superseded, and limits the required actions to engines with an affected DECU P/N installed. This [EASA] AD also prohibits (re)installation of affected DECU on any engine.
>
> This [EASA] AD is revised to provide clarification on affected and serviceable DECU.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0793.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from one individual commenter. The commenter supported the NPRM without change.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD 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 Turbomeca Mandatory Service Bulletin (MSB) No. 319 73 2080, Revision 1, dated February 13, 2004; Turbomeca MSB No. 319 73 2081, Revision 1, dated February 13, 2004; Turbomeca MSB No. 319 73 2082, Revision 1, dated February 13, 2004, Version C, dated July 31, 2008, and Version D, dated June 6, 2011; and Turbomeca MSB No. 319 73 2090, Original Issue, dated February 13, 2004. This service information specifies procedures for upgrading the EECU by either replacing the EECU or by uploading the software to the EECU. These documents are distinct since they apply to different engine models in different configurations. The Director of the Federal Register previously approved Turbomeca MSB No. 319 73 2080, Revision 1, dated February 13, 2004; Turbomeca MSB No. 319 73 2081, Revision 1, dated February 13, 2004; Turbomeca MSB No. 319 73 2082, Revision 1, dated February 13, 2004; and Turbomeca MSB No. 319 73 2090, Original Issue, dated February 13, 2004 for incorporation by reference on June 29, 2005 (70 FR 34334, June 14, 2005). 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**.

Costs of Compliance

The FAA estimates that this AD affects 221 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
Replace the EECU	1 work-hour × $85 per hour = $85	$35,000	$35,085	$7,753,785

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Upgrade the EECU software	2 work-hours × $85 per hour = $170	0	170	37,570

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA has determined that this 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (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 2005–12–08, Amendment 39–14124 (70 FR 34334, June 14, 2005); and

■ b. Adding the following new airworthiness directive:

2021–26–26 Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca S.A.): Amendment 39–21885; Docket No. FAA–2021–0793; Project Identifier MCAI–2021–00372–E.

(a) Effective Date

This airworthiness directive (AD) is effective February 23, 2022.

(b) Affected ADs

This AD replaces AD 2005–12–08, Amendment 39–14124 (70 FR 34334, June 14, 2005).

(c) Applicability

This AD applies to Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca S.A.) Arrius 2B1, Arrius 2B1A, (including those that embody modification (mod) TU45C, identified as Arrius 2B1A_1) and Arrius 2B2 model turboshaft engines with an installed engine electronic control unit (EECU) having part number (P/N) 70EMF01080 or 70EMF01090—for Arrius 2B1 model turboshaft engines without overspeed protection option (TU 19C); P/N 70EMF01100 or P/N 70EMF01120—for Arrius 2B1 model turboshaft engines with overspeed protection option (TU 67C or TU 23C); P/N 70EMH01000 or 70EMH01010—for Arrius 2B1A model turboshaft engines; or P/N 70EMM01000—for Arrius 2B2 model turboshaft engines.

Note 1 to paragraph (c): Turbomeca Mandatory Service Bulletin (MSB) No. 319 73 2082, Version D, dated June 6, 2011, references Arrius 2B1A_1 model turboshaft engines. Arrius 2B1A model turboshaft engines with mod TU 45C applied are identified as Arrius 2B1A_1 on the engine identification plate.

(d) Subject

Joint Aircraft System Component (JASC) Code 7600, Engine Controls.

(e) Unsafe Condition

This AD was prompted by a report of simultaneous loss of automatic control on both engines installed on an Airbus Helicopters Deutschland (formerly Eurocopter Deutschland) EC135 helicopter during flight. The FAA is issuing this AD to prevent simultaneous loss of automatic control of both engines. The unsafe condition, if not addressed, could result in failure of the engines and loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) For engines with an EECU having P/N 70EMF01090, 70EMF01100, 70EMF01120, 70EMH01010, or 70EMM01000, within 90 days after June 29, 2005 (the effective date of AD 2005–12–08), or before further flight, whichever occurs later, upload the EECU software on both engines of the helicopter simultaneously using paragraph 2, Instructions to be incorporated, of the applicable Turbomeca MSB listed in Table 1 to paragraph (g) of this AD, or replace the affected EECU with a part eligible for installation.

(2) For engines with an EECU having P/N 70EMF01080 or 70EMH01000, within 90 days after June 29, 2005 (the effective date of AD 2005–12–08), or before further flight, whichever occurs later, replace the affected EECU with a part eligible for installation.

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Table 1 to paragraph (g) – Applicable MSBs

For—	Use—
Arrius 2B1 engines with EECUs that have incorporated Modification TU 19C	Turbomeca MSB No. 319 73 2080, Revision 1, dated February 13, 2004
Arrius 2B1 engines with EECUs that have incorporated Modification TU 67C or TU 23C	Turbomeca MSB No. 319 73 2081, Revision 1, dated February 13, 2004
Arrius 2B1A and 2B1A1_1 engines	Turbomeca MSB No. 319 73 2082, Revision 1, dated February 13, 2004, Version C, dated July 31, 2008, or Version D, dated June 6, 2011
Arrius 2B2 engines	Turbomeca MSB No. 319 73 2090, Original Issue, dated February 13, 2004

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(h) Installation Prohibition

After the effective date of this AD, do not install onto any engine any EECU having a P/N identified in paragraph (c) of this AD.

(i) Definition

For the purpose of this AD, a ''part eligible for installation'' is an EECU having a P/N that is not identified in paragraph (c) of this AD.

(j) No Reporting Requirements

The reporting requirements specified in Turbomeca MSB No. 319 73 2080, Revision 1, dated February 13, 2004; Turbomeca MSB No. 319 73 2081, Revision 1, dated February 13, 2004; Turbomeca MSB No. 319 73 2082, Revision 1, dated February 13, 2004, Version C, dated July 31, 2008, and Version D, dated June 6, 2011; and Turbomeca MSB No. 319 73 2090, Original Issue, dated February 13, 2004, are not required by this AD.

(k) Alternative Methods of Compliance (AMOCs)

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

(l) Related Information

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

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2021–0088R1, dated July 26, 2021, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0793.

(m) 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.

(3) The following service information was approved for IBR on February 23, 2022.

(i) Turbomeca Mandatory Service Bulletin (MSB) No. 319 73 2082, Version C, dated July 31, 2008.

(ii) Turbomeca MSB No. 319 73 2082, Version D, dated June 6, 2011.

(4) The following service information was approved for IBR on June 29, 2005 (70 FR 34334, June 14, 2005).

(i) Turbomeca MSB No. 319 73 2080, Revision 1, dated February 13, 2004.

(ii) Turbomeca MSB No. 319 73 2081, Revision 1, dated February 13, 2004.

(iii) Turbomeca MSB No. 319 73 2082, Revision 1, dated February 13, 2004.

(iv) Turbomeca MSB No. 319 73 2090, Original Issue, dated February 13, 2004.

(5) For Turbomeca service information identified in this AD, contact Safran Helicopter Engines, S.A., Avenue du 1er Mai, 40220 Tarnos, France; phone: +33 (0) 5 59 74 45 00.

(6) 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 (817) 222–5110.

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

Issued on December 17, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–00891 Filed 1–18–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 12

[Docket No. RM20–9–000; Order No. 880]

Safety of Water Power Projects and Project Works

Correction

In rule document 2021–27736, appearing on pages 1490–1520, in the issue of Tuesday, January 11, 2022, make the following changes:

§ 12.4 [Corrected].

■ 1. On page 1514, in the first column, under amendatory instruction number 3, instruction ''3c'' currently reads, ''Adding paragraphs (b)(2)(iii)(C) and (D);'' should read, ''Revising paragraphs (c)(1), (c)(2) introductory text, and (c)(3); and''

■ 2. On page 1514, in the first column, under amendatory instruction number 3, instruction ''3d'' currently reads, ''Revising paragraphs (c)(1), (c)(2)

introductory text, and (c)(3); and'' should read, ''Adding paragraph (d).''

■ 3. On page 1514, in the first column, under amendatory instruction number 3, instruction ''3e'' should be deleted.

§ 12.10 Reporting safety-related incidents [Corrected].

■ 1. On page 1514, in the third column, amendatory instruction number ''4(b)(5)'' should read ''4(b)(4)''

[FR Doc. C1–2021–27736 Filed 1–18–22; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF STATE

22 CFR Parts 22 and 42

[Public Notice: 11526]

RIN 1400–AF37

Visas: Immigrant Visas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (Department) amends its regulation governing immigrant visa fees to allow for the exemption from immigrant visa (IV) fees for certain applicants previously denied an immigrant visa pursuant to certain Presidential Proclamations issued by the previous administration and associated technical corrections.

DATES: This final rule is effective on January 19, 2022.

FOR FURTHER INFORMATION CONTACT: Claire Kelly, Office of Visa Services, Bureau of Consular Affairs, Department of State, 600 19th St. NW, Washington, DC 20006, (202) 485–7586.

SUPPLEMENTARY INFORMATION:

I. What changes to 22 CFR 22.1, 42.71, and 42.74 does the Department make?

The Department is amending 22 CFR 22.1 and 42.71 to exempt applicants who were denied an IV under section 212(f) of the Immigration and Nationality Act (INA) on or between December 8, 2017, and January 19, 2020, due to Presidential Proclamations 9645 and 9983 (collectively, ''Proc. 9645/9983'') from the payment of immigrant visa fees. The Department is also correcting a typographical error in 22 CFR 22.1, Item 32(e), which should refer to 22 CFR 42.71, *not* 22 CFR 42.74, and correcting the header for § 42.71(b)(2) to specifically refer to adoptees. The Department is also correcting a formatting error in 22 CFR 42.74(a).

II. Policy Justification

On January 20, 2021, President Biden signed Proclamation 10141, ''Ending Discriminatory Bans on Entry to the United States'' (Proc. 10141), which revoked Proc. 9645/9983. Among other requirements, Proc. 10141 directed the Department to create ''a proposal to ensure that individuals whose immigrant visa applications were denied on the basis of the suspension and restriction on entry imposed by Proclamation 9645 or 9983 may have their applications reconsidered'' and that the proposal ''shall consider whether to reopen immigrant visa applications that were denied'' and ''whether it is necessary to charge an additional fee to process those visa applications.''

An IV applicant who is the beneficiary of a valid immigration petition may submit another visa application after being refused and in most circumstances they are required to pay again the relevant application fees. With this final rule, the Department exempts from such fees only those IV applicants who are applying again after being refused an IV pursuant to Proc. 9645/9983, with that limitation on scope being justified by the President's findings articulated in Proc. 10141, as described below. Many IV applicants denied under Proc. 9645/9983, assuming no material change in circumstances, may now be eligible for a visa, and the Department is exempting this defined category of IV applicants from payment of IV fees if they apply again for an immigrant visa.

Some applicants were initially denied IVs under the Proc. 9645/9983 and additional refusal grounds. These applicants are not eligible for the fee exemption established by this final rule, unless a consular officer has previously determined, and informed the applicant in a visa denial letter, that the refusal on other grounds has been overcome and the only impediment to issuance of an IV on January 20, 2021, was Proc. 9645/9983, as reflected in a denial under section 212(f) of the INA, 8 U.S.C. 1182(f). If the other refusal grounds have not been overcome, the applicant will be required to pay the IV fees if they wish to apply again for an immigrant visa.

This final rule also does not apply to IV applicants who were refused due to Proc. 9645/9983 on or after January 20, 2020, as 22 CFR 42.81(e) provides for the reconsideration of their previously filed application, without an additional application fee. That regulation allows IV applicants to have their case reconsidered, without payment of an additional fee, by providing ''further evidence tending to overcome the ground of ineligibility on which the refusal was based'' within one year of the date of refusal. The Department considers Proc. 10141, issued January 20, 2021, as the presentation of evidence overcoming the ineligibility, thus allowing cases refused within the prior year to be reconsidered under 22 CFR 42.81(e) without a new application fee.

Proc. 10141 described Proc. 9645/9983 as ''just plain wrong.'' As a means of remedying a suspension of entry under Proc. 9645/9983 that the President found objectional as explained in Proc. 10141, the Department exempts, from payment of immigrant visa fees, applicants who were denied an IV on or between December 8, 2017, and January 19, 2020, solely due to the Proc. 9645/9983 and who submits a new application for an immigrant visa. Specifically, under this rule, these individuals would be exempt from the applicable immigrant visa application processing fee, as well as the affidavit of support review fee, if the applicant would otherwise be required to pay that fee again.

III. Regulatory Findings and Impact Statements

A. Administrative Procedure Act

This rule is exempt from notice and comment under the Administrative Procedure Act (APA) because it involves a foreign affairs function of the United States. 5 U.S.C. 553(a)(1).

Article II of the Constitution endows the President with certain foreign affairs powers, including the power to regulate the entry of noncitizens to the United States. *See* U.S. CONST. art. II; *United States ex rel. Knauff* v. *Shaughnessy,* 338 U.S. 537, 542 (1950) (''The exclusion of aliens is a fundamental act of sovereignty . . . [and] is inherent in the executive power to control the foreign affairs of the nation.''); *Harisiades* v. *Shaughnessy,* 342 U.S. 580, 588–89 (1952) (''[A]ny policy toward aliens is vitally and intricately interwoven with contemporaneous policies in regard to the conduct of foreign relations [and] the war power . . . .''). An agency action that is taken as an extension of the President's Article II foreign affairs authority is a diplomatic function and falls within the foreign affairs exception (hereafter, the ''exception''). See *East Bay Sanctuary Covenant* v. *Trump,* 932 F.3d 742, 755 (9th Cir. 2018) (noting that Article II ''vests power in the President to regulate the entry of aliens into the United States,'' and are inherent executive powers that constitute a foreign affairs function (citing *Knauff,* 338 U.S. at 542)). Visa functions specifically involve regulating the admission or exclusion of noncitizens. Therefore,

visa-related regulations involve executing a constitutionally-bestowed Executive power. See *Knauff,* 338 U.S. at 542. Any visa-related regulations then fall within the exception as an extension of the President's foreign affairs functions.

An action will fall within the foreign affairs exception if it ''clearly and directly'' involves a foreign affairs function. *Capital Area Immigrants' Rights Coal.* v. *Trump,* 471 F. Supp. 3d 25, 53 (D.D.C. 2020) (''to be covered by the foreign affairs function exception, a rule must clearly and directly involve activities or actions characteristic to the conduct of international relations''). In *Raoof* v. *Sullivan,* the U.S. District Court for the District of Columbia found that the Department properly exercised the foreign affairs exception for the J–1 nonimmigrant visa two-year foreign residence requirement because ''the exchange visitor program—with its statutory mandate for international interaction through nonimmigrants—certainly relates to foreign affairs and diplomatic duties conferred upon the Secretary of State and the State Department.'' 315 F. Supp. 3d 34, 44 (D.D.C. 2018). As in *Raoof,* this rule reflects changes to U.S. foreign policy, specifically in the context of U.S. visas. In waiving certain fees for particular visa applicants, this rule will allow the Department to better facilitate immigration of foreign nationals to the United States, which clearly and directly relates to a foreign affairs function of the United States.

Given the Department's responsibility for carrying out U.S. foreign policy, which includes the issuance of visas, and the Department's discretionary authority to collect visa fees, the Department may exempt categories of foreign nationals from payment of fees for an immigrant visa application. Fees are frequently a central discussion area in bilateral and multilateral consular engagements and have at times become a profound diplomatic irritant. What fees we do or do not charge a given country's citizens will directly affect the fees charged to Americans who wish to visit that country. The Department spends considerable time on this issue, and on ensuring reciprocal treatment for American citizens. Visa fees have a direct diplomatic effect on our relationship with other countries. The Secretary's exercise of a discretionary authority to publicly identify which categories of foreign immigrants are not required to pay immigrant visa application fees, particularly when foreign nationality is a determinant and reciprocal treatment at issue, clearly and directly impact foreign affairs functions of the United States and implicates matters of diplomacy directly. Consequently, in accordance with 5 U.S.C. 553(a)(1), is exempt from the notice and comment requirement of 5 U.S.C. 553.

B. Regulatory Flexibility Act/Executive Order 13272 (Small Business)

As this rulemaking is not subject to notice-and-comment requirements, the Regulatory Flexibility Act does not apply.

C. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UFMA), Public Law 104–4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private section. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

D. Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

The Office of Management and Budget (OMB) has designated this rule a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by OMB.

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Department has reviewed this proposal to ensure consistency with those requirements.

The Department has also considered this rule in light of Executive Order 13563 and affirms that this rule is consistent with the guidance therein.

E. Executive Orders 12372 and 13132 (Federalism)

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders 12372 and 13132.

F. Executive Order 12988 (Civil Justice Reform)

The Department has reviewed the rule in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

G. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

The Department has determined that this rule will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rule.

H. Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

I. Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 801 *et seq.*

List of Subjects in 22 CFR Parts 22 and 42

Consular services, Fees, Immigration, Passports and visas.

Accordingly, for the reasons stated in the preamble, and under the authority 8 U.S.C. 1104 and 22 U.S.C. 2651(a), 22 CFR parts 22 and 42 are amended as follows:

PART 22—SCHEDULE OF FEES FOR CONSULAR SERVICES—DEPARTMENT OF STATE AND FOREIGN SERVICE

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

Authority: 8 U.S.C. 1101 note, 1153 note, 1157 note, 1183a note, 1184(c)(12), 1201(c), 1351, 1351 note, 1713, 1714, 1714 note; 10 U.S.C. 2602(c); 22 U.S.C. 214, 214 note, 1475e, 2504(h), 2651a, 4206, 4215, 4219, 6551; 31 U.S.C. 9701; E.O. 10718, 22 FR 4632, 3 CFR, 1954–1958 Comp., p. 382; E.O. 11295, 31 FR 10603, 3 CFR, 1966–1970 Comp., p. 570.

■ 2. Section 22.1 is amended in the table by revising Item 32(e) and adding Items 32(f) and 34(a) to read as follows:

§ 22.1 Schedule of fees.

* * * * *

SCHEDULE OF FEES FOR CONSULAR SERVICES

Item No.	Fee
* * * * * * *	
32. * * *	
(e) Certain adoptee applicants for replacement Immigrant Visas as described in 22 CFR 42.71(b)(2)	No Fee.
(f) Certain immigrant visa applicants previously refused pursuant to Proclamation 9645 or Proclamation 9983, as described in 22 CFR 42.71(b)(3)	No Fee.
* * * * * * *	
34. * * *	
(a) Certain immigrant visa applicants previously refused solely pursuant to Proclamation 9645 or Proclamation 9983, as described in 22 CFR 42.71(b)(3)	No Fee.
* * * * * * *	

PART 42—VISAS: DOCUMENTATION OF IMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

■ 3. The authority citation for part 42 continues to read as follows:

Authority: 8 U.S.C. 1104 and 1182; Pub. L. 105–277, 112 Stat. 2681; Pub. L. 108–449, 118 Stat. 3469; The Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (done at the Hague, May 29, 1993), S. Treaty Doc. 105–51 (1998), 1870 U.N.T.S. 167 (Reg. No. 31922 (1993)); 42 U.S.C. 14901–14954 (Pub. L. 106–279, 114 Stat. 825); 8 U.S.C. 1101 (Pub. L. 111–287, 124 Stat. 3058); 8 U.S.C. 1154 (Pub. L. 109–162, 119 Stat. 2960); 8 U.S.C. 1201 (Pub. L. 114–70, 129 Stat. 561).

■ 4. Section 42.71 is amended by revising paragraph (b) to read as follows:

§ 42.71 Authority to issue visas; visa fees.

* * * * *

(b) *Immigrant visa fees*—(1) *Payment of fees.* The Secretary of State prescribes a fee for the processing of immigrant visa applications. Except as provided in paragraphs (b)(2) and (3) of this section, an individual registered for immigrant visa processing at a post designated for this purpose by the Deputy Assistant Secretary for Visa Services must pay the fee upon being notified that a visa is expected to become available in the near future, and upon being requested to obtain the supporting documentation needed to apply formally for a visa, in accordance with instructions received with such notification. The fee must be paid before an applicant at a post so designated will receive an appointment to appear and make application before a consular officer. Applicants at a post not yet so designated will pay the fee immediately prior to formal application for a visa. A fee collected for the processing of an immigrant visa application is refundable only if the principal officer of a post or the officer in charge of a consular section determines that the application was not adjudicated as a result of action by the U.S. Government over which the alien had no control and for which the alien was not responsible, which precluded the applicant from benefitting from the processing, or as provided in paragraph (b)(2) of this section.

(2) *Waiver or refund of fees for replacement immigrant visas for adoptees.* The consular officer shall waive the application processing fee for a replacement immigrant visa or, upon request, refund such a fee where already paid, if the consular officer is satisfied that the alien, the alien's parent(s), or the alien's representative has established that:

(i) The prior immigrant visa was issued on or after March 27, 2013, to an alien who has been lawfully adopted, or who is coming to the United States to be adopted, by a United States citizen;

(ii) The alien was unable to use the original immigrant visa during the period of its validity as a direct result of extraordinary circumstances, including the denial of an exit permit; and

(iii) The inability to use the visa was attributable to factors beyond the control of the adopting parent or parents and of the alien.

(3) *Exemption from fees for immigrant visa applicants previously refused solely pursuant to Proclamation 9645 or Proclamation 9983.* An immigrant visa applicant shall be exempt from the application processing fee and the affidavit of support review fee, if the applicant was previously denied an immigrant visa on or between December 8, 2017, and January 19, 2020; the sole ground of ineligibility was based on Proclamation 9645 or 9983; and the applicant is applying again for an immigrant visa. This paragraph (b)(3) provides only for a one-time exemption of the applicable fees per applicant.

■ 5. Section 42.74 is amended by revising paragraph (a) to read as follows:

§ 42.74 Issuance of new, replacement, or duplicate visas.

(a) *New immigrant visa for a special immigrant under INA 101(a)(27)(A) and (B).* The consular officer may issue a new immigrant visa to a qualified alien entitled to status under INA 101(a)(27)(A) or (B), provided that:

(1) The alien establishes that the original visa has been lost, mutilated, or has expired; or that the alien will be unable to use it during the period of its validity; and

(2) The alien pays anew the application processing fees prescribed in the Schedule of Fees (22 CFR 22.1); and

(3) The consular officer ascertains whether the original issuing office knows of any reason why a new visa should not be issued.

* * * * *

Kevin E. Bryant,

Deputy Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2022–00829 Filed 1–18–22; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Parts 523 and 541

[BOP–1176P]

RIN 1120–AB76

FSA Time Credits

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: This rule codifies the Bureau of Prisons' (Bureau or BOP) procedures regarding the earning and application of time credits as authorized by the First Step Act of 2018 (FSA), hereinafter referred to as ''FSA Time Credits'' or ''Time Credits.'' The FSA provides that

eligible inmates earn FSA Time Credits toward prerelease custody or early transfer to supervised release for successfully completing approved Evidence-Based Recidivism Reduction (EBRR) Programs or Productive Activities (PAs) assigned to each inmate based on the inmate's risk and needs assessment. Inmates eligible to apply Time Credits under the FSA include individuals sentenced under the U.S. Code. As required by the FSA, an inmate cannot earn FSA Time Credits if that inmate is serving a sentence for a disqualifying offense or has a disqualifying prior conviction. However, such inmates may still earn other benefits for successfully completing recidivism reduction programming, such as increased privileges (commissary, visiting, and telephone) for participation in EBRR Programs or PAs, as authorized by the Bureau.

DATES: This rule is effective on January 19, 2022.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 353–8248.

SUPPLEMENTARY INFORMATION: This rule codifies the Bureau of Prisons' (Bureau) procedures regarding First Step Act (FSA) Time Credits, as authorized by 18 U.S.C. 3632(d)(4) and Section 101 of the First Step Act of 2018 (Pub. L. 115–391, December 21, 2018, 132 Stat 5194) (FSA). The FSA provides that an eligible inmate in Bureau custody who successfully participates in EBRR Programs or PAs recommended based on the inmate's risk and needs assessment will earn FSA Time Credits, to be applied toward prerelease custody (*i.e.,* transfer to a Residential Reentry Center (RRC) or home confinement for service of a portion of the inmate's sentence) or transfer to supervised release (*i.e.,* early satisfaction of the inmate's term of imprisonment) under 18 U.S.C. 3624(g).

The proposed rule on this subject was published on November 25, 2020 (85 FR 75268). The public comment period ended on January 25, 2021. The Bureau received over two hundred and fifty responses to the publication of the proposed rule, but cannot generate a definite number of comments, as a significant portion of responses were from inmates in Bureau facilities and their family members requesting that FSA Time Credits be applied to the terms of imprisonment of particular inmates, rather than specific comments or questions regarding the proposed regulations as published.

Staff at Bureau facilities have been instructed to address specific questions regarding application of FSA Time Credits to particular inmates with those individual inmates, and we encourage those with questions regarding particular inmates to address those questions to staff at facilities where those inmates are housed, or to the regional offices with oversight for those facilities. A list of Bureau of Prisons Regional Offices can be found on the Bureau website: *https://www.bop.gov/about/facilities/offices.jsp?o=4.*

The Bureau also received a large number of comments on the proposed regulations which repeated certain common themes and issues. We have therefore consolidated the issues raised into representative excerpts from selected commenters, and address these issues below.

Additionally, on October 18, 2021, the Bureau published a document reopening the comment period of the proposed rulemaking until November 17, 2021, to solicit public comment on the limited issue of whether DC Code offenders in Bureau of Prisons custody are eligible to apply Time Credits under 18 U.S.C. 3632(d)(4), as added by the FSA. 86 FR 57612. We received thirty submissions during the reopened comment period with regard to that issue, which we discuss further below.

COMMENT: The Bureau's definition of a ''day'' as one eight-hour-period of a successfully completed EBRR Program or PA is incorrect, unworkable, and/or contrary to congressional intent.

The FSA provides that ''[a] prisoner shall earn 10 days of time credits for every 30 days of successful participation in evidence-based recidivism reduction programming or productive activities.'' 18 U.S.C. 3632(d)(4)(A)(i). An inmate determined to be at a ''minimum or low risk for recidivating'' who, ''over 2 consecutive assessments, has not increased their risk of recidivism, shall earn an additional 5 days of time credits for every 30 days of successful participation in evidence-based recidivism reduction programming or productive activities.'' 18 U.S.C. 3632(d)(4)(A)(ii). The statute does not expressly define what constitutes a ''day'' of successful participation. In the proposed rule, the Bureau defined it as ''one eight-hour period of participation in an EBRR Program or PA that an eligible inmate successfully completes.''

More than 150 commenters raised concerns with the Bureau's definition. For example, Senator Sheldon Whitehouse (D–RI) and Senator John Cornyn (R–TX) commented as follows:

> The proposed rule's definition of a ''day'' of program participation does not adequately reward engagement with [EBBR programs] and PAs consistent with the First Step Act. . . . Because BOP programs do not run for eight hours per day, the proposed rule would require individuals to attend an EBRR or PA for several calendar days before they earned a full ''day'' of time credit. . . It was not our intent as drafters of the legislation that BOP define a ''day'' in this way. Nor did Congress ever consider it. . . . The proposed rule's narrow definition of a ''day'' does not adequately incentivize program participation and reduce recidivism as intended by the First Step Act.

Congressman Hakeem Jeffries (D–NY) echoed the Senators' sentiments, stating:

> [D]efining a day as eight hours of participation does not appear to be a good faith attempt to honor congressional intent. A day of successful participation is clearly a day on which a prisoner has successfully participated in a program or productive activity. BOP[']s definition of [a] day would dramatically reduce the amount of time credits an individual can earn.

RESPONSE: After carefully considering the comments received, the Bureau agrees that a change is warranted. The proposed definition of a day of successful participation was inconsistent with the goals of the FSA and would have been logistically burdensome to calculate and administer. The Bureau is thus adopting a simpler FSA Time Credits program award model that will more fully encourage and reward participation in evidence-based recidivism reduction programs and productive activities.

In enacting the FSA, Congress made clear that Time Credits should be broadly applicable to a wide range of inmates for a broad range of activities to maximize their opportunities to reduce recidivism. The proposed definition, however, would have meant that inmates could successfully do everything asked of them as part of their recommended programming for multiple days (*e.g.,* two hours each day for four days), but be credited for only one day of successful participation.

In addition, the proposed definition would have required Bureau staff to not only track inmate participation in recommended programming, but also break down participation time into individual hours of work, and then aggregate time spent completing certain programming with other time spent completing other programming. This approach would have varied the earning of Time Credits by program factors such as intensity, length, and duration that could have been confusing to inmates, burdensome for staff to administer, and inconsistent with the general goal of awarding Time Credits in a consistent manner to inmates who are participating in the full range of programming

recommended to them based on the results of their risk and needs assessments.

The final rule adopts a more straightforward and more administratively manageable approach that is consistent with the FSA's goal of promoting successful participation in EBRR Programs and PAs. For every thirty-day period that an eligible inmate successfully participates in EBRR Programs or PAs recommended based on the inmate's risk and needs assessment, the inmate will earn ten days of FSA Time Credits. If the inmate is determined to be at a minimum or low risk for recidivating and can maintain that risk level for the most recent two consecutive risk and needs assessments, that inmate may earn an additional five days of FSA Time Credits per thirty-day period.

An eligible inmate must successfully participate in programs and activities that the Bureau recommends based on an individualized risk and needs assessment to earn Time Credits. An inmate will not be considered to be successfully participating if that inmate refuses to participate in or otherwise violates conditions, rules, or requirements of EBRR programs or PAs recommended based on the inmate's risk and needs assessment. However, temporary interruptions in participation that are unrelated to an inmate's refusal to participate or other violation of programming requirements, or that are authorized by the Bureau, such when a recommended program or activity is unavailable or at full enrollment, will not affect the inmate's ability to earn Time Credits.

If an eligible inmate refuses to participate in the recommended program or activity, engages in misconduct that results in removal from the program or activity through placement in restrictive housing, or disrupts or fails to follow the conditions, parameters, or rules of the program or activity, accrual of Time Credits is paused until the inmate complies with programming or completes the disciplinary sanction. This methodology is intended to guide inmates back to the appropriate pro-social goals of programming and act as a deterrent for future misconduct, giving inmates a direct incentive to maintain clear conduct (behavior clear of inmate disciplinary infractions under 28 CFR part 541).

By clarifying the method for awarding Time Credits in this manner to ensure it furthers Congressional intent of the statute, the Bureau hopes to increase the amount of FSA Time Credits that may be awarded to eligible inmates.

COMMENT: FSA Time Credits should be earned for programs successfully completed on or after December 21, 2018, the date of the enactment of the First Step Act, instead of January 15, 2020, as indicated in the proposed rule.

More than 150 commenters raised this issue, including Senator Sheldon Whitehouse (D–RI) and Senator John Cornyn (R–TX), who wrote:

> The Act provides that ''[a] prisoner may not earn time credits under this paragraph for an evidence-based recidivism reduction program that the prisoner successfully completed . . . prior to the date of enactment of this subchapter.'' 18 U.S.C. 3632(d)(4)(B). . . . The proposed rule, however, states that an individual may only earn time credits for programs ''successfully completed on or after January 15, 2020''—more than a year after the date of enactment. Nor does the proposed rule explain why individuals are not eligible to earn time credits for programs completed between December 21, 2018 and January 15, 2020.

Congressman Hakeem Jeffries (D–NY) also commented on this issue, opining that the regulation's proposed start date for earning time credits of January 15, 2020, ''serves no clear purpose and is inconsistent with the text of the First Step Act, which states that credit may not be earned for programs completed prior to the date of enactment of this subchapter, which was December 21, 2018.''

RESPONSE: As the commenters correctly note, the FSA explicitly states that Time Credits may not be earned for participation in programming prior to the date of the FSA's enactment. The statute is silent, however, as to the specific date on which inmates should begin to earn Time Credits. Instead, the statute expressly contemplates a phased-in approach and sets specific timelines and benchmarks for implementation.[1] This phased-in approach is appropriate and warranted, given that the FSA has been the most impactful congressional action taken concerning the Bureau of Prisons in recent years, requiring major changes to existing systems and processes, the development of new systems, and changes that apply to approximately 130,000 current inmates.

Under this phased-in approach, the Attorney General was required to develop and release the risk and needs assessment system within 210 days from the date the FSA was signed into law, December 21, 2018. The new risk and needs assessment tool, called the Prisoner Assessment Tool Targeting Estimated Risk and Needs (PATTERN), was subsequently released on July 19, 2019, in accordance with the FSA. Additional modifications of PATTERN occurred after feedback was received from external stakeholders and the FSA-established Independent Review Committee.

The FSA required that as part of the implementation period, within 180 days of the risk and needs assessment system's release date, the Bureau would conduct initial risk and needs assessments for the inmate population and begin expanding the EBRR Programs and PAs necessary to effectively implement the system.[2] The Bureau assigned an initial PATTERN risk level to each inmate by the statutory deadline of January 15, 2020. And, notably, the Bureau implemented the FSA's directive at 18 U.S.C. 3621(h)(2)(A), to assign inmates to EBRR Programs or PAs by January 15, 2022 (two years after the date by which the agency completed risk and needs assessments for all inmates) well before that date.

Because the FSA contemplates a phase-in period during which the risk and needs assessment system could be developed, and because the FSA is silent regarding a specific date when eligible inmates must begin earning Time Credits, the Bureau exercised its discretion and adopted the position in the proposed rule that it would be reasonable for the Bureau to begin allowing inmates eligible under the FSA to earn FSA Time Credits *after* the risk and needs assessment and relevant programming were established, *i.e.,* on January 15, 2020, the date on which initial evaluations under the new risk and needs assessment system were completed. However, in light of the comments submitted, the Bureau acknowledges that because the FSA is silent regarding a specific date when eligible inmates must begin earning Time Credits, yet explicitly prohibits the earning of Time Credits for participation prior to the date of enactment, the statute could also be interpreted to allow for eligible inmates to earn Time Credits as of December 21, 2018, the date of enactment of the FSA.

[1] *See* 18 U.S.C. 3621(h)(1)(C), referring to the ''risk and needs assessment tools necessary to effectively implement the System over time,'' and sec. 3621(h)(2)(A), requiring that EBRR Programs and PAs be provided ''before the date that is 2 years after the date on which the Bureau of Prisons completes a risk and needs assessment for each prisoner. . . .'' The Bureau completed risk and needs assessments for every inmate in Bureau custody on January 15, 2020, and, therefore, as indicated by the FSA, had until January 15, 2022, to ensure that EBRR Programs and PAs are provided to eligible inmates in Bureau custody. The Bureau was already providing those programs and activities to eligible inmates well in advance of that date.

[2] *See* 18 U.S.C. 3621(h)(1).

The case law on this issue is mixed, but some courts have concluded that this reading is in fact the better one. With regard to participation in programming completed after the date of the FSA's enactment, but before completion of all inmate risk and needs assessments on January 15, 2020, some courts have held that eligible inmates should be awarded FSA Time Credits in addition to the pre-FSA incentives already offered by the Bureau. Courts in the Districts of New Jersey and Oregon have directed the Bureau to award Time Credits under the FSA for the successful completion of programs and activities occurring before January 15, 2020, but on or after December 21, 2018, the FSA's date of enactment. *See, e.g., Cazares* v. *Hendrix,* 20–cv–2019 (D. Or. Nov. 9, 2021); *Goodman* v. *Ortiz,* 2020 WL 5015613, at *6 (D.N.J., Aug. 25, 2020) (holding inmates are currently entitled to FSA Time Credits that have been properly earned); *Hare* v. *Ortiz,* 2021 WL 391280, at *7 (D.N.J. Feb. 4, 2021) (limiting award of Time Credits to those earned for programs completed on or after the date of enactment of the FSA); *Gallo* v. *Ortiz,* Civ. No. 20–16416 (D.N.J., filed Feb. 16, 2021) (District Court required the Bureau to calculate Time Credits based on 2018 date).[3] Awarding Time Credits as of the date of enactment may also be more consistent with the FSA's goals of reducing recidivism through participation in programming and activities, and allowing inmates to work towards early release. From a fairness perspective, the Bureau also acknowledges that an inmate who has been consistently participating in programming, such as working to obtain his or her GED while the FSA was in effect, between December 21, 2018 (the date of the enactment of the FSA), and January 15, 2020 (the date risk and needs assessments were completed on all Bureau inmates), should be rewarded for that effort.

While the Bureau continues to consider the FSA amenable to the interpretation reflected in the proposed rule, it acknowledges that the statute is ambiguous, and in light of the FSA's purposes and fairness considerations, it exercises its discretion to adopt the reading urged by the majority of commenters. Therefore, the Bureau amends this final rule to allow inmates eligible under the First Step Act to receive retroactive Time Credits for programming and activities they participated in starting on December 21, 2018, the date of the FSA's enactment. In determining how to award FSA Time Credits during the period before all individualized risk and needs assessments had been completed, the Bureau faces administrative challenges. Consistent with the phased-in approach contemplated by the FSA, the Bureau did not have mechanisms in place to methodically track participation in EBRRs and PAs until January 15, 2020, because comprehensive uniform tracking codes did not exist. In addition, it was not until that date that the Bureau had completed individualized risk and needs assessments for every inmate—and thus had a basis to conclude that there was an evidence-based reason to assign a particular program to, or recommend particular activities for, an inmate in order to reduce a particular inmate's risk of recidivism. Thus, in many instances, inmates were participating in programs for reasons other than addressing a criminogenic need.

Due to these administrative difficulties, for inmates participating in programming after the date of the FSA's enactment, but before the date that Bureau had completed all risk and needs assessments (December 18, 2018, to January 14, 2020), it is not feasible for the Bureau to connect individual inmate participation in programming to individualized risk and needs assessments, since the risk and needs assessment tool did not exist until well after the date of the FSA's enactment. Instead, for inmate participation in programming during this period of time, the Bureau will exercise its discretion to award FSA Time Credits to inmates otherwise deemed eligible under the First Step Act by applying the same criteria as that applied to inmate participation in authorized EBRR programs or PAs recommended based on a risk and needs assessment after January 2020 to determine the inmate's retroactive Time Credit balance. Eligible inmates will be afforded a presumption of participation for the period between December 21, 2018, and January 14, 2020 and be awarded Time Credits accordingly. Inmates will not receive credit for any period in which they were in a special housing unit, in a designation status outside the institution, temporarily transferred to the custody of another Federal or non-Federal government agency, in mental health/psychiatric holds (either court-ordered mental health/psychiatric evaluations or situations in which mental health or psychiatric evaluation or treatment require an inmate to be designated outside or away from the inmate's ''home'' facility within the Bureau), or for refusing mandatory programming, as further explained below.

COMMENT: There are no safeguards in the risk and needs assessment system to prevent racial discrimination or racial disparities.

Several commenters were concerned about the potential for racial and ethnic biases or disparities in the risk and needs assessment tool used by the Bureau of Prisons.

RESPONSE: The Department of Justice issued the Risk and Needs Assessment System (RNAS) mandated by the First Step Act, known as PATTERN, on July 19, 2019. *See The First Step Act of 2018: Risk and Needs Assessment,* U.S. DEP'T OF JUSTICE: OFFICE OF THE ATTORNEY GENERAL, *https://www.bop.gov/inmates/fsa/docs/the-first-step-act-of-2018-risk-and-needs-assessment-system.pdf* (July 2019). The Department's release of PATTERN was followed by a comment period during which the Department received approximately 200 comments and statements and held two listening sessions. On November 19, 2019, the Attorney General met with the Independent Review Committee (IRC) created by Section 107 of the FSA to discuss proposed changes to PATTERN, as required by 18 U.S.C. 3632.

The Attorney General then announced enhancements to PATTERN in a document entitled *The First Step Act of 2018: Risk and Needs Assessment System—UPDATE, https://www.bop.gov/inmates/fsa/docs/the-first-step-act-of-2018-risk-and-needs-assessment-system-updated.pdf* (January 2020) (2020 Update). In this 2020 Update, and in response to concerns arising from potential racial disparities, the Department instituted several recommended changes to the tool. Later, in 2021, the Department also implemented a more standardized

[3] Most courts that have analyzed this issue, however, have found it reasonable for the Bureau to begin awarding Time Credits for successful completion on or after January 15, 2020, as opposed to holding that inmates are entitled to FSA Time Credits for successful completion of EBRR Programs and PAs occurring before that date but on or after December 21, 2018. *See, e.g., Cohen* v. *United States,* No. 20–cv–10833, 2021 WL 1549917, at *6 (S.D.N.Y. Apr. 20, 2021) (''[T]he statute does not require the BOP to begin awarding ETCs [earned time credits] during the phase-in period.''); *Kennedy-Robey* v. *Warden, FCI Pekin,* No. 20–cv–1371 (C.D. Ill. Mar. 2, 2021) (ECF No. 14) (''Not only is the BOP's decision to delay awarding credits permitted under the statute, the BOP has legitimate reasons for desiring to do so.''); *Llewlyn* v. *Johns,* No. 5:20-cv-77, 2021 WL 535863 (S.D. Ga. Jan. 5, 2021); *Herring* v. *Joseph,* No. 4:20–CV–249, 2020 WL 3642706, at *1 (N.D. Fla. July 6, 2020); *Holt* v. *Warden,* 4:20–CV–04064–RAL, (D.S.D. May. 13, 2021; *Fleming* v. *Joseph,* No. 3:20CV5.990–LC–HTC, 2021 WL I66936I (N.D. Fla. Apr. 7, 2021) (report and recommendation). *See also Bowling* v. *Hudgins,* 2020 WL 1917490 (N.D. Va. Apr. 20, 2020); *Allen* v. *Hendrix,* 2020 WL 890396 (E.D. Ark. Feb. 24, 2020).

process for inputting scores into the risk and needs system, and the Bureau will continue to ensure that necessary precautions are taken to ensure consistent, objective application for all inmates in accordance with the published schema.

The *2021 Annual Review and Revalidation of the First Step Act Risk Assessment Tool* report confirmed the predictive and dynamic validity of PATTERN, but expressed the concern that differences in race and ethnicity might affect predictions of risk for recidivism. The Justice Department takes seriously its responsibility under the First Step Act to annually ''review, validate, and release publicly on the Department of Justice website the risk and needs assessment system,'' and ''. . . to identify any unwarranted disparities, including disparities among similarly classified prisoners of different demographic groups . . .'' 18 U.S.C. 3631(b)(4)(E). The Department will continue to meet this mandate, to rigorously evaluate any risk assessment tool, including through the use of outside experts, and to take all steps possible to address and mitigate against racial bias or other disparities.

As part of that compliance, the Department will publish annually (1) for each disqualifying offense, data on how many individuals from each racial and/or ethnic group were ineligible to earn Time Credits; (2) for each disqualifying prior federal conviction, data on how many individuals from each racial and/or ethnic group were ineligible to earn Time Credits; (3) for all other disqualifying prior convictions, data on how many individuals from each racial and/or ethnic group were ineligible to earn Time Credits; (4) data on how many individuals from each racial and/or ethnic group were eligible to earn Time Credits; and (5) how many individuals from each racial and/or ethnic received risk and needs assessment score classifications of ''high,'' ''medium,'' ''low,'' and ''minimum'' based on their most recent assessment.

COMMENT: The Bureau does not have the resources to implement the FSA Time Credits program appropriately.

Several commenters were concerned about the Bureau's ability to implement the FSA Time Credits program. One commenter, for example, stated that ''the average course that is offered by BOP is not listed on the list for reentry courses, some of which are college/correspondence courses that inmates have to pay for out of pocket. As for the courses that are listed, they are not even offered at this time because inmates are the teachers of them, and COVID does not allow inmates to teach them at this time. Many inmates are returning home now, not having had any reentry courses—not to their own fault.'' Other commenters mentioned long waitlists and other scarcity of resource issues.

RESPONSE: The Bureau recognizes the significant impact that the FSA will have on inmate programming, and notes that additional appropriated funding has been directed toward FSA implementation. These additional resources will be used to add to existing programs and meet the FSA's direction that the Bureau encourage and increase inmate programming participation.

Before the enactment of the FSA, the Bureau already offered a wide variety of programs and activities designed to prepare inmates for release, educate them, and provide them with substance abuse disorder and mental health treatment. The Bureau has always endeavored to focus on increasing the breadth and depth of its programming for inmates and build greater capacity for inmate participation in programming, and the FSA provides further statutory support for that mission. To that end, the Bureau has asked, and will continue to ask, Congress to authorize funding and staffing for those purposes, and will endeavor to fill staff positions as necessary to increase and enhance inmate programming.

In *The First Step Act of 2018: Risk and Needs Assessment System—UPDATE,* U.S. DEP'T OF JUSTICE: OFFICE OF THE ATTORNEY GENERAL, *https://www.bop.gov/inmates/fsa/docs/the-first-step-act-of-2018-risk-and-needs-assessment-system-updated.pdf* (January 2020) (2020 Update), the Department indicated that it had received feedback expressing concerns about the Bureau's programming capacity. *Id.* at 18. The issue raised by this feedback to the Department is substantially similar to concerns raised by the commenters on the Bureau's proposed rule.

In response to the feedback discussed in this 2020 Update, the Department described the waitlist process for inmate programming, indicating that that process is meant to ensure that inmates are ''enrolled in needed courses at the appropriate times in their incarceration,'' and that ''case management and programming staff monitor these lists based on inmate need and release date/plans, to ensure relevant programs are completed in appropriate timeframes.'' *Id.* The Department also described the ongoing expansion of Federal Prison Industries and the Resolve Program (providing trauma treatment). However, the Department also noted:

> As part of the FSA implementation, the BOP is assigning codes to approved evidence-based recidivism reduction programs and productive activities to enable tracking and monitoring of their capacity and use. BOP will also begin assigning inmates to specific programs to address identified needs, which will allow it to further examine inmate interest and program capacity. Based upon these changes, BOP can expand or contract capacity consistent with the inmate needs and interests.

Id. The Department also noted in the 2020 Update that the Bureau had ''already begun expanding programs and hiring staff to deliver'' further necessary programming, and that although the FSA, issued in 2018, had ''not come with appropriated funds in [fiscal year] FY 2019 . . . BOP had taken the initiative to adjust funding within its budget to cover a variety of targeted FSA activities.'' Further, for FY 2020, approximately $116 million was authorized to allow the Bureau to expand evidence-based reentry programs, capacity for prerelease custody, medication-assisted treatment (MAT) for opioid use disorder nationwide, information technology services for inmates, and evaluation of programs and services. *Id.* at 21–22.

Additionally, in the 2020 Update, the Department noted that to facilitate implementation of the FSA, the Bureau had increased staffing at female institutions and enhanced male and female trauma treatment and vocational training offerings. The Bureau also implemented a variety of hiring strategies to address staffing shortfalls, and continues to do so. *Id.* at 24. Therefore, while the Bureau recognizes that resources have been strained, future funding allotments will enhance the Bureau's course offerings and serve to bolster the Bureau's resources, improving its ability to carry out the FSA Time Credits program across all Bureau facilities.

COMMENT: FSA Time Credits should be awarded for participation in UNICOR, online or correspondence college courses, religious services, more time for RDAP, and other programs and activities.

Several commenters suggested that the list of EBRR Programs and PAs should be expanded to include participation in, or a greater amount of Time Credits allowable for participation in, UNICOR and prison jobs, online or correspondence courses (including college courses), religious services, the Residential Drug Abuse Treatment Program (RDAP), and a variety of other programs, courses, and activities.

For instance, one commenter indicated that while the requirement to successfully complete a program before earning Time Credits ''may make sense for educational classes, certificate-based programs, or fixed length productive activities, it should not apply to prison jobs that would require ongoing accumulation of Time Credits. A prison job is not a 'program to complete,' has no set duration, and its success is based on continued employment and supervisor evaluations.''

Another commenter suggested that those ''participating in the Residential Drug[] Abuse Program (RDAP), should receive (16) program hours per day, 2 eight-hour program days for 1 proposed day, . . . [because] RDAP participants 'live' in a therapeutic community.''

Additionally, Senator Sheldon Whitehouse (D–RI) and Senator John Cornyn (R–TX) commented as follows:

> As BOP finalizes and implements its proposed rule, it should ensure that individuals are assigned to categories of programs that meet their needs, rather than specific programs, to allow for maximum participation in credit-earning EBRRs and PAs. . . . Each program at a facility should be appropriately categorized, including faith-based programs. Such flexibility will ensure that individuals can freely choose to participate or not participate in faith-based options. It is also critical to allow for greater program access as BOP expands its offerings, as some programs have limited capacity or may not be offered at particular facilities.

RESPONSE: The Bureau agrees with these commenters, and has structured its programs and work assignments to promote participation and flexibility. New funding allotments will enhance the Bureau's course offerings, largely by permitting it to increase capacity through hiring additional staff, and will also serve to bolster the Bureau's resources, thereby improving its ability to carry out the FSA Time Credits program. The Bureau began to enhance programming immediately after the FSA's enactment, using then-current appropriations from FY 2019 not allotted specifically for FSA implementation, and continued to grow its programming offerings with budget allotments as authorized from FY 2020 appropriations.

In *The Attorney General's First Step Act Section 3634 Annual Report,* U.S. DEP'T OF JUSTICE: OFFICE OF THE ATTORNEY GENERAL, *https://www.bop.gov/inmates/fsa/docs/20201221_fsa_section_3634_report.pdf* (December 2020) (2020 Annual Report), the Bureau established a review process to consider externally submitted programs for potential inclusion on the approved EBRR Program/PA list. *Id.* at 17. The Bureau currently engages in partnerships with external organizations to recruit community volunteers to assist with inmate reentry and educational programs. Consistent with the goal of supporting and expanding volunteer activities at all institutions, on June 25, 2019, the Bureau provided guidance to all Wardens about the importance and use of partnerships under the FSA. Specifically, the Assistant Directors for the Office of General Counsel and Reentry Services Divisions issued guidance on collaboration with outside organizations pursuant to the FSA. This memorandum provided information on the FSA's statutory requirements, the Bureau process for establishing partnerships, equitable treatment of similar organizations, and tracking of partnerships.

On September 19, 2019, voluntary partnerships were in place at all 122 Bureau institutions. During FY 2019, 5,939 individuals volunteered 110,489 hours at various institutions. During FY 2020 (as of September 10, 2020), 5,978 volunteers and contractors had provided 157,752 hours at various institutions. The increase in volunteer hours can, in part, be attributed to staff efforts to increase partnerships pre-COVID–19, and changes made to the Bureau volunteer tracking system. *Id.* at 37.

In 2020, the Bureau created unique identifier codes for every Bureau program. These codes allow Bureau to track inmates' program enrollment, participation, and completion. This information can then be compared to needs assessment information and used as a method for assessing capacity. Unfortunately, because of the global pandemic, the Bureau has not been able to program as it would under normal conditions.

The Bureau assesses 12 broad need areas plus dyslexia, and programs are matched to each of these needs. As normal operations resume, the Bureau will be able to accurately track whether inmates sign up for the programs that match their needs, and whether the programs are offered with enough capacity that inmates are able to complete them at the appropriate times during their sentences. While the Bureau's current list of over 70 EBRR Programs and PAs addresses most areas of need, some improvements have been made even during the pandemic. For example, the Bureau created better quality and more standardized materials that provide more consistent program delivery. Additionally, a more intensive program addressing criminal cognition is in development to account for this highly prevalent need in Bureau facilities. *Id.* at 19–20.

Also, several programs and activities mentioned by the commenters as items that should be included in the list of approved programs are, in fact, already on the list. *The First Step Act Approved Programs Guide,* available on the Bureau's website at *https://www.bop.gov/inmates/fsa/docs/2021_fsa_program_guide.pdf* (Programs Guide), contains a program description, institution locations, needs addressed by each program offered, and the department responsible for program delivery (*e.g.,* Education, Psychology).

The Programs Guide indicates that offered programs and activities ''will vary based on the needs of the sentenced population'' at a given location. This helps to explain, in part, why some programs and activities may not be available at all facilities. However, as the Bureau continues to expand its offerings, the Programs Guide continues to expand, and will be updated annually.

With regard to several programs and activities specifically mentioned by commenters:

UNICOR: Employment in Federal Prison Industries (FPI, also known by its trade name, UNICOR) is included in the Programs Guide as an EBRR Program.

RDAP: The Residential Drug Abuse Treatment Program (RDAP), is included in the Program Guide as an EBRR Program.

Online or correspondence college courses: The Programs Guide includes Post-Secondary Education programming, and explains that ''[c]ollege level classes are provided by credentialed instructors from the community who deliver coursework leading to the Associates or Bachelors degree,'' and that ''[s]pecific prerequisites for each program are determined by the school providing the service.'' *See Programs Guide* at 23. This program, delivered by Education staff or appropriately credentialed contractors, allows for online or correspondence college courses, as authorized and credentialed by the Bureau's Education staff.

Religious services and programming: The Programs Guide describes several faith-based programs and activities currently available at all Bureau facilities, including the Threshold Program, a faith-based reentry program (*id.* at 32), and Embracing Interfaith Cooperation, a PA which fosters interfaith dialogue and understanding to counter religious discrimination and extremism (*id.* at 36).

Also, the Bureau's longstanding Life Connections Program (LCP), a

residential, multi-faith-based reentry program open to inmates of all religious traditions and those with no faith affiliation, uses contract partners to provide religious services, while community volunteers serve as mentors to inmate participants. This program is available at six Bureau facilities. *See* 2020 Annual Report, *supra,* at 37–38.

As the Bureau's FSA implementation budget appropriations increase and necessary COVID–19 pandemic-related health and safety restrictions ease, the Bureau will continue its efforts to expand EBRR programming and PA offerings available at Bureau facilities for eligible inmates. Furthermore, as noted above, the Bureau has changed the proposed regulation to a more inclusive model, whereby FSA Time Credits may be earned if an eligible inmate is successfully participating in EBRR Programs and PAs recommended based upon his or her risk and needs assessment. Also, inmates will not be penalized if specifically recommended EBRR Programs or PAs are unavailable to them or at full enrollment at their facilities. As the Bureau continues to evaluate these and other types of programs and activities, the list of EBRR Programs and PAs for which inmates may earn FSA Time Credits will likewise increase.

COMMENT: FSA Time Credits should be earned for successful participation, not only for successful completion.

Many commenters opined that FSA Time Credits should be awarded on an ongoing basis, during *participation* in EBRR programming and PAs, instead of after successful *completion* of an EBRR Program or PA. One commenter wrote that

> [b]y focusing only on completion, BOP diminishes the value of participation and weakens the incentive structure Congress enacted. Indeed, there are myriad situations where people would successfully participate in an approved program and—through no fault of their own—be prevented from, or delayed in, completing it. Transfers, program resource and staffing limitations, and facility movement restrictions all impact program completion, as do length of sentence, program availability, and waitlists. Individuals have no control over completion if, for example, their facility is locked down, or if programs are indefinitely suspended due to a pandemic. Congress created the earned time credit system to encourage personal responsibility. BOP's all-or-nothing rule that fails to acknowledge participation is inconsistent with this intent. BOP should revise the proposed rule to allow individuals who successfully participate in programming to earn time credits.

RESPONSE: The Bureau agrees with these comments. As indicated previously, the Bureau is altering and expanding its method for awarding Time Credits.

The concern of the commenters regarding participation in programming echoes the Bureau's longstanding policy of encouraging inmate reentry programming and productive activities throughout each inmate's incarceration, which is consistent with the FSA's goal of attaining maximum recidivism reduction. The Bureau will continue to emphasize the need for full and successful participation in EBRR programs and PAs, as recommended for each inmate, to achieve the maximum award of FSA Time Credits to the maximum number of eligible inmates.

Toward that end, the Bureau has developed the simpler model which it now adopts for the FSA Time Credits program. Under this model, each eligible inmate earns Time Credits while participating in recommended EBRR Programs and PAs. Time Credits for successful participation are awarded at the end of each thirty-day period. By altering the scheme for awarding Time Credits in this manner, the Bureau hopes to increase the amount of FSA Time Credits that may be awarded to the maximum number of eligible inmates. Inmates must participate in all programs and activities that the Bureau recommends based on an individualized risk and needs assessment to be considered to have successfully participated in recommended EBRR Programs and PAs for purposes of earning Time Credits.

It is important to note, however, that temporary interruptions in participation that are unrelated to an inmate's refusal or other violation of programming requirements, such as the unavailability of a recommended program or activity or its full enrollment, or interruptions authorized by the Bureau, will not affect the inmate's ability to earn Time Credits. An inmate's ability to earn FSA Time Credits will be affected if the inmate refuses to participate in the recommended programming or productive activity, engages in misconduct that results in removal from the program or activity through placement in restrictive housing, or disrupts or fails to follow the conditions, parameters, or rules of the activity. In the event that the inmate is found to have committed any of these violations, accrual of Time Credits is paused until the inmate complies with programming conditions, parameters, or rules, or completes the disciplinary sanction.

For, example, the Bureau may permit an inmate to continue earning FSA Time Credit if programming is briefly interrupted due to an instructor's illness, which results in the instructor canceling class for the day. Another possible example might be a brief interruption caused by an inmate requiring to be absent from programming for a day or two due to illness or medical treatment. In such circumstances, the Bureau may review whether or not the illness or medical treatment is attributable to factors over which the inmate may exercise control (possible drug overdose, injuries sustained while fighting, etc.), whether the conduct is a disciplinary offense, or whether it is excusable behavior and therefore may be authorized. The Bureau will strive to reach an equitable result when calculating time in program participation and circumstances both beyond and within the inmate's control.

Accordingly, unless the inmate formally declines recommended programming addressing his or her unique needs, or is not participating in any activities, the assumption is that the eligible inmates will be earning Time Credits and fully participating in recommended programming. The regulation indicates that accrual of Time Credits may be suspended in certain situations when the inmate is unable to participate in recommended programming, including, but not limited to, situations such as:

- Placement in a Special Housing Unit;
- Designation status outside the institution (*e.g.,* for extended medical placement in a hospital or outside institution, court appearances, an escorted trip, a furlough, etc.);
- Temporary transfer to the custody of another federal or non-federal government agency (e.*g.,* on state or federal writ, transfer to state custody for service of sentence, etc.);
- Placement in mental health/psychiatric holds; or
- ''Opting out'' (choosing not to participate in the EBRR programs or PAs that the Bureau has recommended based on the inmate's individualized risk and needs assessment).

Inmates who decline to participate in a recommended voluntary EBRR or PA (*i.e.,* inmates that ''opt out'') will not be considered to be refusing a program assignment for the purposes of disciplinary prohibited act code violations, but will merely be excluded from benefits or privileges of FSA Time Credit Program participation. For example, declining to take a recommended anger management course will prevent an inmate from earning FSA Time Credits, but will not in itself constitute a disciplinary prohibited act code violation. Inmates that refuse a formal assignment,

however, will also be held responsible for any attendant disciplinary prohibited act code violations, *e.g.,* failing to report to institution work detail.[4]

COMMENT: FSA Time Credits should be applied to an inmate's transfer to supervised release (to shorten a term of imprisonment).

Some commenters indicated that they were concerned that Time Credits would not, in fact, be applied to transfer to supervised release at all, but instead might only be applied to prerelease custody, noting that the proposed rule ''does not address the procedures for determining whether an individual inmate will have FSA Time Credits applied toward prerelease custody, early transfer to supervised release, a combination of both, or neither; this proposed rule only addresses the procedures for earning, awarding, loss, and restoration of FSA Time Credits.''

RESPONSE: As stated, under the FSA, an eligible inmate who successfully participates in an EBRR Program or PA recommended by staff based on the inmate's risk and needs assessment may earn FSA Time Credits to apply toward prerelease custody or transfer to supervised release. Eligible inmates may earn 10 days of Time Credits (and, if maintaining a low or minimum risk status, an additional 5 days of Time Credits) for every 30-day period of successful participation in EBRR Programs or PAs.

However, under the FSA (18 U.S.C. 3624(g)), even if earned, Time Credits may not be applied to prerelease custody until:

- The amount of earned Time Credits is equal to the remainder of the inmate's imposed term of imprisonment;
- The inmate has demonstrated a reduced risk of recidivism or maintained a minimum or low recidivism risk during his or her term of imprisonment;
- The remainder of the inmate's imposed term of imprisonment has been computed under applicable law (*e.g.,* Good Conduct Time Credit under 28 CFR part 523 has been applied, eligibility for early release consideration under Residential Drug Abuse Treatment Program regulations in 28 CFR part 550 has been evaluated, etc.); and
- The inmate has been determined to be at a minimum or low risk of recidivating based on his or her last two assessments, or has had a petition to be transferred to prerelease custody approved by the warden.

Similar requirements exist under the FSA for application of earned Time Credits to transfer to supervised release. Time Credits may not be applied to transfer to supervised release under 18 U.S.C. 3624(g) unless:

- The amount of earned Time Credits is equal to the remainder of the inmate's imposed term of imprisonment;
- The inmate's sentence includes a period of supervised release to be served after his or her term of imprisonment;
- The inmate's latest risk and needs assessment shows that he or she is at a minimum or low risk of recidivating; and
- The application of Time Credits would not result in starting the period of supervised release more than 12 months before he or she would otherwise be eligible to do so (*i.e.,* any amount of earned Time Credits in excess of 12 months would be applied to prerelease custody).

See Nathan James, U.S. Congressional Research Service, The First Step Act of 2018: An Overview (2019), at 5–6.

The Bureau assures commenters that FSA Time Credits will be applied to early transfer to supervised release, as authorized by the FSA in 18 U.S.C. 3632(d)(4)(C) and 18 U.S.C. 3624(g). *See* 2020 Annual Report at 39–44. The Bureau intends to adhere to the parameters of the FSA to permit application of Time Credits toward transfer to supervised release pending development of policy, in individual cases as appropriate.

COMMENT: Earning FSA Time Credits should continue in Residential Reentry Centers and/or while in home confinement.

Many commenters raised an issue that was articulated by Senator Sheldon Whitehouse (D–RI) and Senator John Cornyn (R–TX) as follows:

> The proposed rule also provides that ''FSA Time Credits can only be earned while an inmate is in a Bureau facility, and will not be earned if an inmate is in a Residential Reentry Center or on home confinement.'' The proposed rule does not cite to any authority for this restriction, and this interpretation is not consistent with the goals of the First Step Act.
>
> Allowing individuals to earn time credits while in RRCs is authorized by the First Step Act. The Act provides that ''[t]ime credits earned . . . by prisoners who successfully participate in recidivism reduction programs or productive activities shall be applied toward time in prerelease custody or supervised release.'' It defines ''prisoner'' as ''a person who has been sentenced to a term of imprisonment pursuant to a conviction for a Federal criminal offense, or a person in the custody of the Bureau of Prisons.''
>
> Because ''[p]re-release inmates at an RRC remain in Federal custody while serving a sentence imposed by a U.S. District Court or DC Superior Court,'' they are ''prisoners'' for the purposes of the First Step Act. Nor does the First Step Act distinguish between ''prisoners'' who are serving their sentence in a BOP institution, in an RRC, or on home confinement in describing the time credit program. By its own terms, the statute allows BOP to award time credits to individuals incarcerated in an RRC toward time in supervised release.
>
> Allowing individuals incarcerated in an RRC to earn time credits by participating in EBRRs would further the purposes of the First Step Act. RRCs offer substance abuse treatment and other programs similar to those offered in BOP institutions. There is no reason to believe that a program offered in an RRC will reduce recidivism any less than one offered to an individual in prison. In fact, such programs may be more effective, as individuals are close to release from custody and can begin putting lessons learned into practice as they transition home. BOP should revise the proposed rule to allow individuals to earn time credits while in an RRC.

Congressman Hakeem Jeffries (D–NY) also stated, ''I see no reason to make individuals in Residential Reentry Centers (RRCs) or in home confinement ineligible to earn time credits. . . . Congress could have used a narrower definition or explicitly excluded certain categories of individuals based on where they serve their sentence, but it chose not to do so.''

RESPONSE: After carefully considering the comments received, the Bureau agrees that inmates in prerelease custody—whether in a residential reentry center (RRC) or on home confinement—are eligible to earn FSA Time Credits under 18 U.S.C. 3632(d)(4)(A), which they could presumably apply, under 18 U.S.C. 3632(d)(4)(C), toward transfer to supervised release.

The practical effect of allowing eligible inmates to keep earning Time Credits while in prelease custody (RRCs) will likely be limited, however, for several reasons. First, the Bureau intends to transfer eligible inmates who satisfy the criteria in 3624(g) to supervised release to the extent practicable, rather than to prelease custody. The Bureau therefore anticipates that the total population of eligible inmates in RRCs or home confinement will be small.

Second, as a practical matter, programming and services for inmates in RRCs or home confinement will often be provided off-site or by a third-party provider, which makes tracking successful participation more difficult. For example, community-based substance use treatment programs referred to by the Senators in their

[4] *See* 28 CFR 541.3, Table 1—Prohibited Acts and Available Sanctions: Moderate Severity Level Prohibited Acts, code 306: ''Refusing to work or to accept a program assignment.''

comments are not provided on-site at RRCs, but rather on an outpatient basis. The Bureau uses a comprehensive inmate information tracking system that is only accessible to Bureau staff. The Bureau's inmate information tracking system is not accessible to RRC staff, and therefore cannot track inmate programming activity when inmates are no longer in the custody of the Bureau of Prisons.

Third, unlike a prison facility, which is a self-contained unit under the Bureau's control and supervision that can provide Bureau-authorized, comparable, and approved programming to all housed inmates, the breadth of programming available at or through different RRCs, or in the communities where an inmate may be place in home confinement, could vary significantly and may not correspond directly to recommendations based on inmates' most recent risk and needs assessments.

Given these variables, the Bureau will work on a case-by-case basis with eligible inmates in RRCs to identify appropriate available programming for them to earn FSA Time Credits, and will determine how to best track participation as part of the Bureau's commitment to ensure the maximum number of FSA Time Credits may be awarded to the maximum number of eligible inmates. The Bureau will issue guidance on this topic to ensure consistency in implementation.

COMMENT: All inmates should be eligible for FSA Time Credits without exclusions.

Several commenters recommended that, as a general matter, any inmate willing to participate in the FSA Time Credit program should be eligible for FSA Time Credits. A few individual commenters suggested more specifically that inmates convicted of particular offenses (as described above) should be removed from the category of ''ineligible prisoners,'' as described in 18 U.S.C. 3632(d)(4)(D), and should be permitted to earn FSA Time Credits for application toward prerelease custody or transfer to supervised release.

RESPONSE: As noted, 18 U.S.C. 3632(d)(4)(D) describes inmates that are ''ineligible to receive time credits'' under Subchapter D (the Risk and Needs Assessment System) if serving a term of imprisonment for conviction under any of the provisions listed therein. It is outside the Bureau's authority to alter the exclusions as stated in the FSA. Some commenters suggested that ''non-violent'' offenses be removed from the ineligibility exclusions, but did not specify which offenses listed might be considered ''non-violent'' or otherwise define that term. Regardless, the statutory exclusions may only be amended by Congress.

Specific offenses: The FSA enumerates 68 offenses for which inmates who are serving terms of imprisonment are ineligible. Commenters raised several specific offenses. We note that under the FSA's list of 68 enumerated offenses, the following are included as ones for which inmates are ineligible if they are serving a term of imprisonment upon conviction:

- 18 U.S.C. 2250, relating to failure to register as a sex offender (*see* 18 U.S.C. 3632(d)(4)(D)(xxxviii));
- 18 U.S.C. 2251, relating to the sexual exploitation of children (*see* 18 U.S.C. 3632(d)(4)(D)(xxxix));
- 18 U.S.C. 2251A, relating to the selling or buying of children (*see* 18 U.S.C. 3632(d)(4)(D)(xl));
- 18 U.S.C. 2252, relating to certain activities concerning material involving the sexual exploitation of minors (*see* 18 U.S.C. 3632(d)(4)(D)(xli));
- 18 U.S.C. 2252A, relating to certain activities involving material constituting or containing child pornography (*see* 18 U.S.C. 3632(d)(4)(D)(xlii));
- 18 U.S.C. 2260, relating to the production of sexually explicit depictions of a minor for importation into the United States (*see* 18 U.S.C. 3634(d)(4)(D)(xliii)).

Prior convictions: As stated in the preamble to the proposed rule, an inmate cannot earn FSA Time Credits if he or she has a disqualifying prior conviction as specified in 18 U.S.C. 3632(d)(4)(D). In the interest of clarifying the statement in the proposed rule, a ''disqualifying prior conviction'' would render an inmate ineligible to earn Time Credits under 18 U.S.C. 3632(d)(4)(D)(li) if the inmate:

1. Had a *prior conviction* for which he or she served a term of imprisonment of more than 1 year, for a Federal or State offense, by whatever designation and wherever committed, consisting of the following:

- Murder (as described in 18 U.S.C. 1111),
- voluntary manslaughter (as described in 18 U.S.C. 1112),
- assault with intent to commit murder (as described in 18 U.S.C. 113(a)),
- aggravated sexual abuse and sexual abuse (as described in 18 U.S.C. 2241 and 2242),
- abusive sexual contact (as described in 18 U.S.C. 2244(a)(1) and (a)(2)),
- kidnapping (as described in 18 U.S.C. chapter 55),
- carjacking (as described in 18 U.S.C. 2119),
- arson (as described in 18 U.S.C. 844(f)(3), (h), or (i)), or
- terrorism (as described in 18 U.S.C. chapter 113B);

AND

2. Is currently serving a term of imprisonment of more than 1 year for an offense described in 18 U.S.C. 3559(c)(2)(F), *i.e.,* a ''serious violent felony,'' which means either—

(i) a Federal or State offense, by whatever designation and wherever committed, consisting of the following:

- Murder (as described in 18 U.S.C. 1111);
- manslaughter other than involuntary manslaughter (as described in 18 U.S.C. 1112);
- assault with intent to commit murder (as described in 18 U.S.C. 113(a));
- assault with intent to commit rape (as described in 18 U.S.C. 3559(c)(2)(A));
- aggravated sexual abuse and sexual abuse (as described in 18 U.S.C. 2241 and 2242);
- abusive sexual contact (as described in 18 U.S.C. 2244(a)(1) and (a)(2));
- kidnapping (as described in 18 U.S.C. 3559(c)(2)(E));
- aircraft piracy (as described in 49 U.S.C. 46502);
- robbery (as described in 18 U.S.C. 2111, 2113, or 2118);
- carjacking (as described in 18 U.S.C. 2119);
- extortion (as described in 18 U.S.C. 3559(c)(2)(C));
- arson (as described in 18 U.S.C. 3559(c)(2)(B));
- firearms use (as described in 18 U.S.C. 3559(c)(2)(D));
- firearms possession (as described in 18 U.S.C. 924(c));
- or attempt, conspiracy, or solicitation to commit any of the above offenses;

OR

(ii) any other offense punishable by a maximum term of imprisonment of 10 years or more—

- that has as an element the use, attempted use, or threatened use of physical force against the person of another or
- that, by its nature, involves a substantial risk that physical force against the person of another may be used in the course of committing the offense.

The Bureau is cognizant of the strict categorical analysis required by the Supreme Court in adjudicating whether an offense meets the elements or residual clause of 18 U.S.C. 3559. As such, the Bureau after consultation with the Department of Justice will ensure that its facilities receive updated information as to which federal and state offenses qualify or are the subject

of litigation and that inmate records are updated to ensure maximum participation in credit-earning EBRRs.

Deportable inmates: As the FSA also indicates in 18 U.S.C. 3632(d)(4)(E), an inmate who is subject to a final order of removal under immigration laws as defined in 8 U.S.C. 1101(a)(17) may not have FSA Time Credits applied toward prerelease custody or early transfer to supervised release under 18 U.S.C. 3624(g).

Although the Bureau does not have the authority to award FSA Time Credits to inmates who are ineligible under the FSA, such inmates may still earn other benefits for successfully participating in the many other types of programming offered by the Bureau. Inmates ineligible for earning or applying FSA Time Credits may still receive incentives such as increased privileges (commissary, visiting, and telephone) for participation in EBRR Programs.

COMMENT: Forfeiture penalties for earned Time Credits are too severe.

Many commenters stated that the proposal to amend the Bureau's regulations on inmate discipline in 28 CFR part 541 to include forfeiture of FSA Time Credits as a disciplinary sanction was too severe. One commenter stated that:

> The forfeiture rates would be too harsh on their own, but even more punitive when combined with other negative consequences for violations, including limits on future earning and use of time credits and would be disproportionately severe across all levels of prohibited acts... Moreover, forfeiture of earned time credits is not the only consequence an individual would suffer as the result of a prison infraction. An infraction could also negatively affect an individual's ability to earn and use time credits in the future by raising his risk score. . .

Another commenter stated that

> The proposed rule provides that to restore credits from prison rule violations, an individual must first have ''[c]lear conduct for at least four consecutive risk and needs assessments.''. . . It could take at least 4 years to complete ''at least four consecutive risk and needs assessments.'' Yet BOP provides no justification for requiring clear conduct for this long. Indeed, requiring an individual to remain infraction-free for at least 4 years is inconsistent with PATTERN. Under PATTERN, individuals who are infraction-free for 12 months or more receive no points related to the recency of an infraction. If PATTERN indicates those with infractions older than 12 months are no more risky than those with infractions older than 4 years, it is difficult to understand what justification BOP would have to require ''clear conduct'' for what could be at least 4 years.

RESPONSE: The Bureau agrees with these commenters, and has adjusted the proposed penalties related to FSA Time Credits accordingly. As stated in the proposed rule, FSA Time Credits may be lost through inmate discipline procedures described in 28 CFR part 541 only if an inmate violates the requirements or rules of an EBRR Program or PA. The FSA authorizes the Bureau to develop procedures for the reduction of FSA Time Credits for inmates under these circumstances. *See* 18 U.S.C. 3632(e). Opting out of a program will not result in the forfeiture of credits, unless failure to complete the program itself constitutes an infraction (*e.g.* failing to accept a mandatory work assignment).

The Bureau's proposed amendments to 28 CFR 541.3, Table 1 (Prohibited Acts and Available Sanctions), were intended to resemble the structure of current sanctions for loss of Good Conduct Time, which allow for forfeiture in escalating amounts depending on the severity level of the prohibited act committed. However, in light of the comments received, the Bureau alters the proposed forfeiture sanctions to more closely mirror the Good Conduct Time forfeiture sanctions, and accordingly decreases the amount of FSA Time Credits forfeiture sanctions for each prohibited act severity level offense by more than half.

Further, upon review, the Bureau agrees with commenters that it is inconsistent with the risk and needs assessment methodology to require clear conduct (behavior clear of inmate disciplinary infractions under 28 CFR part 541) for four consecutive assessments to permit restoration of forfeited Time Credits, and therefore alters the regulation to maintain consistency with the Department of Justice risk and needs assessment methodology—requiring clear conduct for *two* consecutive assessments (one year) as a condition of restoring forfeited Time Credits.

COMMENT: The FSA should be applicable to DC Code Offenders.

The Bureau reopened the comment period of the proposed rulemaking from October 18, 2021, until November 17, 2021, to solicit public comment on the limited issue of whether DC Code offenders in Bureau of Prisons custody are eligible to apply Time Credits under 18 U.S.C. 3632(d)(4), as added by the FSA. 86 FR 57612. We received thirty submissions during the reopened comment period. However, of those submissions, only eighteen were comments relating to the limited issue. Twelve submissions related to issues raised during the proposed rule comment period in 2020 or to specific circumstances of particular inmates in Bureau facilities and their eligibility for FSA Time Credits, rather than the limited issue for which the document reopened the comment period. As we stated above with regard to submissions unrelated to the proposed rule, we encourage those with questions regarding particular inmates to address those questions to staff at facilities where those inmates are housed, or to the regional offices with oversight for those facilities.

RESPONSE: The October 18, 2021 document indicated that the proposed rule would have expressly excluded from time-credit eligibility any inmate serving a term of imprisonment only for an offense under the laws of the District of Columbia. The FSA, however, is ambiguous as to whether those with convictions under the DC Code are eligible to apply FSA Time Credits through their participation in EBRR programs or PAs.

Some comments pointed to features of the statute's text or history, suggesting that Congress intended DC Code offenders to be eligible to apply FSA Time Credits to their sentences. A comment from the Public Defender Service for the District of Columbia noted that the FSA defines ''prisoner'' as ''a person who has been sentenced to a term of imprisonment pursuant to a conviction for a Federal criminal offense, or a person in the custody of the Bureau of Prisons.'' 18 U.S.C. 3635(4). That definition includes DC Code offenders, who the commenter pointed out are in Bureau custody under the National Capital Revitalization and Self Government Improvement Act of 1997, which requires that ''any person who has been convicted of a felony offense pursuant to the District of Columbia Code . . . shall be subject to any law or regulation applicable to persons committed for violations of laws of the United States consistent with the sentence imposed.'' 111 Stat. 251 at 734; Public Law 105–33, Sec. 11021 (the ''DC Revitalization Act'').

A comment from Senator Cory Booker (D–NJ) noted that other unenacted bills addressing similar subjects that preceded the enactment of the FSA would have defined ''prisoner'' as a person sentenced for a federal offense. *See* Corrections and Recidivism Reduction Act of 2016, H.R. 759, 114th Cong. 8(4) (as introduced Feb. 5, 2015 sub nom. Recidivism Risk Reduction Act), *https://www.congress.gov/bill/114th-congress/house-bill/759/text/ih* (defining ''prisoner'' as ''a person who has been sentenced to a term of imprisonment pursuant to a conviction for a Federal criminal offense''); the Sentencing Reform and Corrections Act

of 2015, S. 2123, 114th Cong. 202(b)(8) (as introduced Oct. 1, 2015), *https://www.congress.gov/bill/114th-congress/senate-bill/2123/text/is* (defining ''eligible prisoner'' as ''a prisoner serving a sentence of incarceration for conviction of a Federal offense,'' with exceptions for medical and security circumstances and sentences under one month).

But there are other statutory features suggesting Congress may not have intended the FSA Time Credit program to alter the time that DC Code offenders spend in Bureau facilities while serving sentences imposed by the District of Columbia. As noted, the DC Revitalization Act commits DC Code offenders to Bureau custody, but provides that these offenders ''shall be subject to any law or regulation applicable to'' U.S. Code offenders only insofar as those laws or regulations are ''consistent with the sentence imposed.'' (DC Code section 24–101(b).) While this restriction does not appear to bar DC Code offenders from earning FSA Time Credits, it does appear to bar them from applying those credits in a way that would change the duration of their DC-imposed sentences, *i.e.,* by granting them early supervised release. Even given this limitation that currently exists by virtue of the DC Code, it is possible that Congress intended to permit DC Code offenders to use Time Credits to secure an early transfer to prerelease custody, which does not change the sentence's duration. But the fact that at least part of the FSA Time Credit program is inconsistent with the terms on which the DC Code has committed DC Code felons to Bureau custody suggests otherwise.

In addition, Congress took care to preclude violent U.S. Code offenders from using FSA Time Credits to secure an early release from Bureau facilities, specifying a long list of serious Federal crimes in 18 U.S.C. 3632(d)(4)(D), a conviction for which makes a prisoner ineligible to earn Time Credits.[5] Congress's failure to provide an analogous list of serious DC Code offenses could indicate that Congress did not intend DC Code offenders to be eligible to apply Time Credits. Similarly, the FSA states that the Time Credit system does not apply ''with respect to offenses committed before November 1, 1987,'' (*see* Section 102(b)(3) of the FSA), which is the date Federal parole was abolished, but does not contain any like provision for the date DC parole was abolished (2000). If the FSA is construed to afford DC Code offenders in Bureau custody a right to apply Time Credits, Congress's failure to account for the date on which DC parole was abolished would mean that some DC Code offenders could be eligible for both parole and the FSA Time Credit program. Congress could have acted to avoid the overlap of these two programs, and the fact that Congress did not do so could further suggest that Congress did not intend the FSA to make DC Code offenders eligible to apply Time Credits.

Finally, there is a textual basis for concluding that Congress did not intend the FSA to make DC Code offenders eligible to use Time Credits. In Section 105 of the FSA, Congress provided that nothing in the FSA ''may be construed to provide authority to place a prisoner in prerelease custody or supervised release who is serving a term of imprisonment pursuant to a conviction for an offense under the laws of one of the 50 States, or of a territory or possession of the United States.'' 18 U.S.C. 3621 Note. As a comment (from the DC Justice Lab, Democracy Forward Foundation, FAMM, Justice Action Network, National Association of Criminal Defense Lawyers, Washington Lawyers' Committee for Civil Rights, and Urban Affairs) noted, it is unclear whether the District of Columbia is ''one of the 50 States,'' a ''territory,'' or a ''possession'' of the United States. The Bureau agrees that Section 105 is ambiguous; statutory references to States and territories may or may not be understood to include the District of Columbia, depending on the statutory context. *See, e.g., District of Columbia* v. *Carter,* 409 U.S. 418, 420 (1973). Particularly in light of the statutory features above, Section 105 could be read to manifest Congress's desire to avoid interference with non-U.S. Code sentences of offenders who end up in Bureau custody.

Overall, there is significant ambiguity about whether and to what extent DC Code offenders are eligible to apply FSA Time Credits under the statute. A construction of the FSA that would allow DC Code offenders to apply Time Credits under federal law would create particular concerns because of the absence of any basis on which to preclude DC Code offenders convicted of violent crimes from then using Time Credits. That result would substantially diverge from the FSA provision that expressly bars federal inmates convicted of any one of a list of 68 categories of enumerated violent offenses (only one of which includes any DC Code offenses, and only under certain conditions, see 18 U.S.C. 3632(d)(4)(D)(li)) from receiving FSA Time Credits. Although the majority of the comments received during the reopened comment period supported allowing DC Code offenders to earn FSA Time Credits, they largely failed to address the issue of whether violent DC Code offenders should be eligible to apply such credits along with non-violent offenders. A single comment received during the reopened comment period opposed application of the FSA to DC Code offenders in Bureau custody, expressing concern that the rule would ''undermine the criminal justice system and allow these violent offenders to re-enter society to only most likely commit these violent crimes again.'' The lack of additional discussion in the comments regarding this issue is particularly problematic because the overwhelming majority of DC offenders in Bureau custody are serving sentences for violent offenses analogous to the list of offenses that disqualify federal offenders from receiving FSA Time Credits.

The Bureau is also concerned that adopting a reading of the FSA to permit DC Code offenders to leave Bureau facilities before they have served their DC-imposed sentences stands in some tension with other provisions of the DC Code. In other circumstances, where the length of a DC Code offender's sentence would be reduced, there are specific authorities in the DC Code to authorize such actions. For example, the DC Code specifies that offenders sentenced to imprisonment for felonies committed after August 5, 2000, ''may receive good time credit toward service of the sentence only as provided in 18 U.S.C. 3624(b)'' (DC Code section 24–403.01(d)); that those sentenced to imprisonment after August 5, 2000, ''for a nonviolent offense may receive up to a one-year reduction'' for completing a substance-abuse-treatment program in accordance with 18 U.S.C. 3621(e)(2) (DC Code section 24–403.01(d–1)(1)); and that certain DC Code offenders who committed their crimes before age 25 have an opportunity to be resentenced to a reduced term (DC Code section 24–403.03). There are no similar provisions to allow DC Code offenders to have sentences reduced by early placement on supervised release under the terms of the FSA.

Many of these considerations implicate the sovereignty of the District of Columbia and its authority over DC Code offenders and could be addressed through local legislation. The Bureau further understands that the DC Council is actively considering whether and

[5] *See, e.g.,* 164 Cong. Rec. S7642 (daily ed. Dec. 17, 2018) (statement of Sen. Cornyn) (''There are some who, for example, say that this legislation will put violent criminals and sex offenders back on the streets, which is completely false. . . . This bill will not allow dangerous, violent criminals to be released early. . . . We have disqualified violent offenders . . . .'').

under what circumstances DC Code offenders should be eligible for FSA Time Credits as a matter of DC law. The Council has the authority and latitude to incorporate the FSA Time Credit program by reference into the DC Code and specify which DC Code offenders are eligible to apply FSA Time Credits. The DC Council may, for example, develop a list of excluded DC Code offenses that parallels the list of violent federal offenses in 18 U.S.C. 3632(d)(4)(D), or otherwise clarify whether and in what circumstances inmates may apply Time Credits toward pre-release custody and/or supervised release. Should the Council enact legislation that speaks to the issues presented by the FSA's ambiguity, such legislation could significantly inform, or dictate, the relevance of the FSA's time-credit program to DC Code offenders in the Bureau's custody.

In light of these statutory interpretation and policy considerations, and the current deliberations of the DC Council, the Bureau will defer definitively resolving the FSA's ambiguities with respect to DC Code offenders in its custody. The final rule therefore is amended to reflect the possibility that the DC Council will enact legislation regarding the eligibility of such offenders to apply FSA Time Credits. Thus, any inmate in Bureau custody who is sentenced to a term of imprisonment under the Criminal Code of the District of Columbia is, at present, not eligible to apply FSA Time Credits unless the laws of the District of Columbia are amended to authorize the application of such credits. The Bureau may revisit this question through future rulemaking, depending on the outcome of the DC Council's consideration of these issues, and any other relevant developments.

Regulatory Certifications

Executive Orders 12866 and 13563: Because this proposed rule may raise novel legal or policy issues arising out of implementation of the First Step Act, the Office of Management and Budget (OMB) has determined that it constitutes a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and has reviewed it.

The economic impact of this rule is limited to a specific subset of inmates who are eligible to earn and apply FSA Time Credits toward additional prerelease custody or early transfer to supervised release. Under the FSA, FSA Time Credits may be earned by an eligible inmate who is assessed to have a minimum or low risk for recidivating and who has had no increased risk of recidivism over the most recent two consecutive assessments conducted by the Bureau. Consistent with the FSA, inmates in Bureau custody are assessed under its risk and needs assessment system, which includes both static and dynamic elements.

For example, on August 27, 2020, 131,386 inmates had been assessed under the risk and needs assessment tool and received a risk and needs assessment score. The risk and needs assessment scores for the entire group of 131,386 inmates were: 50,060 classified as high; 25,043 classified as medium; 38,084 classified as low; and 18,199 classified as minimum. Of these inmates, approximately 65,000 would be ineligible to earn FSA Time Credits under the FSA due to the inmate's crime of conviction. This data represents a snapshot of those inmates in Bureau custody as of August 27, 2020.

The Bureau conducted risk and needs assessments for Federal inmates and assigned EBRR Programs by the January 15, 2020, FSA deadline. As of that date, recidivism risk assessment levels of High, Medium, Low, or Minimum were assigned to all sentenced inmates at Bureau designated facilities. The Bureau anticipates that this data will change continually, as inmates in custody earn reductions in risk classification, based on program participation and other dynamic factors, and inmates enter and release from Bureau custody.

The Bureau anticipates that as a result of this rule and the FSA, additional inmates will engage in programming to earn FSA Time Credits. As discussed above, FSA Time Credits may be earned for successful completion of an EBRR Program or PA that is assigned to an inmate based on the inmate's needs assessment. The current list of these programs can be found at *https://www.bop.gov/inmates/fsa/docs/2021_fsa_program_guide.pdf.* These programs are available to all inmates regardless of an inmate's eligibility to earn FSA Time Credits.

The rule may also result in movement of eligible inmates who earn FSA Time Credits from Bureau facilities to prerelease custody in the community (including RRCs and home confinement) earlier in the course of their confinement and for a longer period of time than would have previously occurred. In some cases, this transfer of time from secured confinement to prerelease custody may result in increased costs, depending on the relative costs of the inmate's current facility and the costs associated with housing or supervision in prerelease custody.

The rule may also result in the early transfer of inmates from custody to supervised release, functionally shortening their term of imprisonment. In such cases, the Bureau would avoid costs that would otherwise have been incurred to confine the affected inmates for that amount of time.

At present, therefore, specific monetary costs or savings for these future actions cannot be calculated. But, consistent with the purpose of the statute, the proposed rule will enhance public safety and reduce the need for future incarceration by providing significant incentives to encourage inmates to participate in evidence-based programs intended to reduce their risk of recidivism and help facilitate their successful reentry back into society after they have served their time.[6]

For these reasons, it is not possible to forecast the actual economic effect of this rule. However, given the mix of cost increases and savings which may result, the overall long-term economic impact is expected to be marginal in either direction.

The purpose of this rule is to codify the Bureau's procedures regarding the earning and application of time credits as authorized by the FSA. Time credits may be applied towards prerelease custody or early transfer to supervised release, and some inmates will be eligible for such custody or release as soon as this rule goes into effect. Delaying implementation for 30 days could therefore deprive at least some inmates of time in the less restrictive environments that Congress has determined are appropriate for eligible inmates. Given the liberty issues implicated by the prompt implementation of this program and this rule, the Bureau is prepared to begin implementation immediately, and the Bureau therefore finds good cause for exempting this rule from the provision of the Administrative Procedure Act (5 U.S.C. 553(d)) which ordinarily requires a delay in effective date. The Bureau notes that neither it nor the affected inmates require a delay to adjust their practices before this rule takes effect. A delay in the effective date of this final rule would be unnecessary and contrary to the public interest.

Executive Order 13132: This rule will not have 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

[6] The costs or cost savings resulting from this rule will not be fully realized for years to come, as increasing numbers of inmates have opportunities to earn FSA Time Credits over their terms of incarceration, are transferred to prerelease custody or supervised release, and reintegrate into the community.

levels of government. Therefore, under Executive Order 13132, we determine that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act: The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this rule and certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This rule pertains to the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

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

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

For the foregoing reasons, we issue the regulations regarding the First Step Act Time Credits, proposed on November 25, 2020, with modifications, as set forth below.

List of Subjects in 28 CFR Parts 523 and 541

Prisoners.

Michael D. Carvajal,

Director, Federal Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons in 28 CFR 0.96, we amend 28 CFR parts 523 and 541 as follows:

Subchapter B—Inmate Admission, Classification, and Transfer

PART 523—COMPUTATION OF SENTENCE

■ 1. The authority citation for 28 CFR part 523 is revised to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3568 (repealed November 1, 1987, as to offenses committed on or after that date), 3621, 3622, 3624, 3632, 3635, 4001, 4042, 4081, 4082 (repealed in part as to conduct occurring on or after November 1, 1987), 4161–4166 (repealed October 12, 1984, as to offenses committed on or after November 1, 1987), 5006–5024 (repealed October 12, 1984, as to conduct occurring after that date), 5039; 28 U.S.C. 509, 510.

■ 2. Add subpart E to read as follows:

Subpart E—First Step Act Time Credits

Sec.

§ 523.40 Purpose.

(a) The purpose of this subpart is to describe procedures for the earning and application of Time Credits as authorized by 18 U.S.C. 3632(d)(4) and Section 101 of the First Step Act of 2018 (Pub. L. 115–391, December 21, 2018, 132 Stat. 5194) (FSA), hereinafter referred to as ''FSA Time Credits'' or ''Time Credits.''

(b) Generally, as defined and described in this subpart, an eligible inmate who successfully participates in Evidence-Based Recidivism Reduction (EBRR) Programs or Productive Activities (PAs) that are recommended based on the inmate's risk and needs assessment may earn FSA Time Credits to be applied toward prerelease custody or early transfer to supervised release under 18 U.S.C. 3624(g).

§ 523.41 Definitions.

(a) *Evidence-Based Recidivism Reduction (EBRR) Program.* An EBRR Program is a group or individual activity that has been shown by empirical evidence to reduce recidivism or is based on research indicating that it is likely to be effective in reducing recidivism; and is designed to help prisoners succeed in their communities upon release from prison. EBRR Programs may include, but are not limited to, those involving the following types of activities:

(1) Social learning and communication, interpersonal, anti-bullying, rejection response, and other life skills;

(2) Family relationship building, structured parent-child interaction, and parenting skills;

(3) Classes on morals or ethics;

(4) Academic classes;

(5) Cognitive behavioral treatment;

(6) Mentoring;

(7) Substance abuse treatment;

(8) Vocational training;

(9) Faith-based classes or services;

(10) Civic engagement and reintegrative community services;

(11) Inmate work and employment opportunities;

(12) Victim impact classes or other restorative justice programs; and

(13) Trauma counseling and trauma-informed support programs.

(b) *Productive Activity (PA).* A PA is a group or individual activity that allows an inmate to remain productive and thereby maintain or work toward achieving a minimum or low risk of recidivating.

(c) *Successful participation.* (1) An eligible inmate must be ''successfully participating'' in EBRR Programs or PAs to earn FSA Time Credits for those EBRR Programs or PAs.

(2) ''Successful participation'' requires a determination by Bureau staff that an eligible inmate has participated in the EBRR programs or PAs that the Bureau has recommended based on the inmate's individualized risk and needs assessment, and has complied with the requirements of each particular EBRR Program or PA.

(3) Temporary operational or programmatic interruptions authorized by the Bureau that would prevent an inmate from participation in EBRR programs or PAs will not ordinarily affect an eligible inmate's ''successful participation'' for the purposes of FSA Time Credit eligibility.

(4) An eligible inmate, as described in paragraph (d) of this section, will generally not be considered to be ''successfully participating'' in EBRR Programs or PAs in situations including, but not limited to:

(i) Placement in a Special Housing Unit;

(ii) Designation status outside the institution (*e.g.,* for extended medical placement in a hospital or outside institution, an escorted trip, a furlough, etc.);

(iii) Temporary transfer to the custody of another Federal or non-Federal government agency (*e.g.,* on state or Federal writ, transfer to state custody for service of sentence, etc.);

(iv) Placement in mental health/psychiatric holds; or

(v) ''Opting out'' (choosing not to participate in the EBRR programs or PAs that the Bureau has recommended based on the inmate's individualized risk and needs assessment).

(5)(i) If an eligible inmate ''opts out,'' or chooses not to participate in any of the EBRR programs or PAs that the Bureau has recommended based on the inmate's individualized risk and needs assessment, the inmate's choice must be documented by staff.

(ii) Opting out will not, by itself, be considered a disciplinary violation. However, violation of specific requirements or rules of a particular recommended EBRR Program or PA, including refusal to participate or withdrawal, may be considered a disciplinary violation (*see* this part).

(iii) Opting out will result in exclusion from further benefits or privileges allowable under the FSA,

until the date the inmate ''opts in'' (chooses to participate in the EBRR programs or PAs that the Bureau has recommended based on the inmate's individualized risk and needs assessment, as documented by staff).

(d) *Eligible inmate*—(1) *Eligible to earn FSA Time Credits.* An inmate who is *eligible to earn* FSA Time Credits is an *eligible inmate* for the purposes of this subpart. Any inmate sentenced to a term of imprisonment pursuant to a conviction for a Federal criminal offense, or any person in the custody of the Bureau, is *eligible to earn* FSA Time Credits, subject to the exception described in paragraph (d)(2) of this section.

(2) *Exception.* If the inmate is serving a term of imprisonment for an offense specified in 18 U.S.C. 3632(d)(4)(D), the inmate is not *eligible to earn* FSA Time Credits.

§ 523.42 Earning First Step Act Time Credits.

(a) *When an eligible inmate begins earning FSA Time Credits.* An eligible inmate begins earning FSA Time Credits after the inmate's term of imprisonment commences (the date the inmate arrives or voluntarily surrenders at the designated Bureau facility where the sentence will be served).

(b) *Dates of participation in EBRRs or PAs.* (1) An inmate cannot earn FSA Time Credits for programming or activities in which he or she participated before December 21, 2018, the date of enactment of the First Step Act of 2018.

(2) An eligible inmate, as defined in this subpart, may earn FSA Time Credits for programming and activities in which he or she participated from December 21, 2018, until January 14, 2020.

(3) An eligible inmate, as defined in this subpart, may earn FSA Time Credit if he or she is successfully participating in EBRR programs or PAs that the Bureau has recommended based on the inmate's individualized risk and needs assessment on or after January 15, 2020.

(c) *Amount of FSA Time Credits that may be earned.* (1) For every thirty-day period that an eligible inmate has successfully participated in EBRR Programs or PAs recommended based on the inmate's risk and needs assessment, that inmate will earn ten days of FSA Time Credits.

(2) For every thirty-day period that an eligible inmate has successfully participated in EBRR Programs or PAs recommended based on the inmate's risk and needs assessment, that inmate will earn an additional five days of FSA Time Credits if the inmate:

(i) Is determined by the Bureau to be at a minimum or low risk for recidivating; and

(ii) Has maintained a consistent minimum or low risk of recidivism over the most recent two consecutive risk and needs assessments conducted by the Bureau.

§ 523.43 Loss of FSA Time Credits.

(a) *Procedure for loss of FSA Time Credits.* An inmate may lose earned FSA Time Credits for violation of the requirements or rules of an EBRR Program or PA. The procedures for loss of FSA Time Credits are described in 28 CFR part 541.

(b) *How to appeal loss of FSA Time Credits.* Inmates may seek review of the loss of earned FSA Time Credits through the Bureau's Administrative Remedy Program (28 CFR part 542).

(c) *Restoration of FSA Time Credits.* An inmate who has lost FSA Time Credits under this subpart may have part or all of the FSA Time Credits restored to him or her, on a case-by-case basis, after clear conduct (behavior clear of inmate disciplinary infractions under 28 CFR part 541) for two consecutive risk and needs assessments conducted by the Bureau.

§ 523.44 Application of FSA Time Credits.

(a) *How Time Credits may be applied.* For any inmate eligible to earn FSA Time Credits under this subpart who is:

(1) Sentenced to a term of imprisonment under the U.S. Code, the Bureau may apply FSA Time Credits toward prerelease custody or supervised release as described in paragraphs (c) and (d) of this section.

(2) Subject to a final order of removal under immigration laws as defined in 8 U.S.C. 1101(a)(17) (*see* 18 U.S.C. 3632(d)(4)(E)), the Bureau may not apply FSA Time Credits toward prerelease custody or early transfer to supervised release.

(3) Serving a term of imprisonment pursuant to a conviction for an offense under laws other than the U.S. Code (see Section 105 of the FSA, Pub. L. 115–391, 132 Stat. 5214 (not codified; included as note to 18 U.S.C. 3621)), the Bureau may not apply FSA Time Credits toward prerelease custody or early transfer to supervised release. This paragraph (a)(3) will not bar the application of FSA Time Credits, as authorized by the DC Code, for those serving a term of imprisonment for an offense under the DC Code.

(b) *Consideration for application of FSA Time Credits.* Where otherwise permitted by this subpart, the Bureau may apply FSA Time Credits toward prerelease custody or early transfer to supervised release under 18 U.S.C. 3624(g) only if an eligible inmate has:

(1) Earned FSA Time Credits in an amount that is equal to the remainder of the inmate's imposed term of imprisonment;

(2) Shown through the periodic risk reassessments a demonstrated recidivism risk reduction or maintained a minimum or low recidivism risk, during the term of imprisonment; and

(3) Had the remainder of his or her imposed term of imprisonment computed under applicable law.

(c) *Prerelease custody.* The Bureau may apply earned FSA Time Credits toward prerelease custody only when an eligible inmate has, in addition to satisfying the criteria in paragraph (b) of this section:

(1) Maintained a minimum or low recidivism risk through his or her last two risk and needs assessments; or

(2) Had a petition to be transferred to prerelease custody or supervised release approved by the Warden, after the Warden's determination that:

(i) The prisoner would not be a danger to society if transferred to prerelease custody or supervised release;

(ii) The prisoner has made a good faith effort to lower their recidivism risk through participation in recidivism reduction programs or productive activities; and

(iii) The prisoner is unlikely to recidivate.

(d) *Transfer to supervised release.* The Bureau may apply FSA Time Credits toward early transfer to supervised release under 18 U.S.C. 3624(g) only when an eligible inmate has, in addition to satisfying the criteria in paragraphs (b) and (c) of this section:

(1) An eligible inmate has maintained a minimum or low recidivism risk through his or her last risk and needs assessment;

(2) An eligible inmate has a term of supervised release after imprisonment included as part of his or her sentence as imposed by the sentencing court; and

(3) The application of FSA Time Credits would result in transfer to supervised release no earlier than 12 months before the date that transfer to supervised release would otherwise have occurred.

Subchapter C—Institutional Management

PART 541—INMATE DISCIPLINE AND SPECIAL HOUSING UNITS

■ 3. The authority citation for part 541 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4161–4166 (Repealed as

to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 4. Amend § 541.3 in paragraph (b), Table 1, by:

■ a. Under the heading ''Available Sanctions for Greatest Severity Level Prohibited Acts'', adding the entry B.2 in alphanumeric order;

■ b. Under the heading ''Available Sanctions for High Severity Level Prohibited Acts'', adding the entry B.2 in alphanumeric order;

■ c. Under the heading ''Available Sanctions for Moderate Severity Level Prohibited Acts'', adding the entry B.2 in alphanumeric order; and

■ d. Under the heading ''Available Sanctions for Low Severity Level Prohibited Acts'', adding the entry B.2 in alphanumeric order.

The additions read as follows:

§ 541.3 Prohibited acts and available sanctions.

* * * * *

(b) * * *

TABLE 1—PROHIBITED ACTS AND AVAILABLE SANCTIONS

* * * * * * *	
Available Sanctions for Greatest Severity Level Prohibited Acts	
* * * * * * *	
B.2	Forfeit up to 41 days of earned First Step Act (FSA) Time Credits (*see* 28 CFR part 523, subpart E) for each prohibited act committed.
* * * * * * *	
Available Sanctions for High Severity Level Prohibited Acts	
* * * * * * *	
B.2	Forfeit up to 27 days of earned FSA Time Credits for each prohibited act committed.
* * * * * * *	
Available Sanctions for Moderate Severity Level Prohibited Acts	
* * * * * * *	
B.2	Forfeit up to 14 days of earned FSA Time Credits for each prohibited act committed.
* * * * * * *	
Available Sanctions for Low Severity Level Prohibited Acts	
* * * * * * *	
B.2	Forfeit up to 7 days of earned FSA Time Credits (only where the inmate is found to have committed a second violation of the same prohibited act within 6 months; forfeit up to 14 days of FSA Time Credits (only where the inmate is found to have committed a third violation of the same prohibited act within 6 months).
* * * * * * *	

* * * * *

■ 5. Amend § 541.7 by revising paragraph (f) to read as follows:

§ 541.7 Unit Discipline Committee (UDC) review of the incident report.

* * * * *

(f) *Sanctions.* If you committed a prohibited act or prohibited acts, the UDC can impose any of the available sanctions in Tables 1 and 2 of § 541.3, except loss of good conduct time credit, FSA Time Credits, disciplinary segregation, or monetary fines.

[FR Doc. 2022–00918 Filed 1–14–22; 4:15 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0535; FRL–9444–02–R5]

Air Plan Approval; Wisconsin; Wisconsin Nonattainment New Source Review Certification for the 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving, as a State Implementation Plan (SIP) revision, Wisconsin's certification that its SIP satisfies the nonattainment new source review (NNSR) requirements of the Clean Air Act (CAA) for the 2015 ozone National Ambient Air Quality Standard (NAAQS).

DATES: This direct final rule will be effective March 21, 2022, unless EPA receives adverse comments by February 18, 2022. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0535 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted,

comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, *etc.*) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Rachel Rineheart, Environmental Engineer, Air Permit Section, Air Programs Branch (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7017, *rineheart.rachel@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

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

I. What is EPA's evaluation of Wisconsin's submittal?

A. Background

On July 27, 2021, Wisconsin submitted a SIP revision requesting that EPA approve Wisconsin's certification that its existing SIP-approved NNSR regulations fully satisfy the NNSR requirements set forth in 40 CFR 51.165 for all areas not attaining the 2015 Ozone NAAQS. Wisconsin has certified that specific sections of its NNSR rules at NR 408 continue to meet the NNSR requirements for ozone nonattainment areas under the 2015 ozone NAAQS. Table 1 below provides the sections of Wisconsin's NNSR rule corresponding to the relevant requirements at 40 CFR 51.165. NR 408 was originally approved into the SIP effective February 17, 1995,[1] with revisions subsequently approved into the SIP effective January 16, 2009.[2] Each requirement identified in Wisconsin's certification has not been revised since EPA last approved it. Table 1 lists the specific provisions of Wisconsin's NNSR rules that address the required elements of the Federal NNSR rules:

TABLE 1—REQUIRED ELEMENTS

Federal rule	Wisconsin rule
40 CFR 51.165(a)(1)(iv)(A)(1)(i)–(iv)	NR 408.02(21), NR 408.02(21)(a)(1)(b), (c), (d), and (e).
40 CFR 51.165(a)(1)(iv)(A)(2)	NR 408.02(21)(b), NR 408.02(21)(b)(1)(a)–(c), and NR 408.02(21)(b)(2)–(4).
40 CFR 51.165(a)(1)(iv)(A)(3)	NR 408.02(21)(a)(3).
40 CFR 51.165(a)(1)(v)(E)	NR 408.02(20)(c).
40 CFR 51.165(a)(1)(v)(F)	NR 408.02(20)(a).
40 CFR 51.165(a)(1)(x)(A)	NR 408.02(32)(a) and NR 408.02(32)(a)(6).
40 CFR 51.165(a)(1)(x)(B)	NR 408.02(32)(c).
40 CFR 51.165(a)(1)(x)(C)	NR 408.02(32)(f) and NR 408.03(5).
40 CFR 51.165(a)(1)(x)(E)	NR 408.02(32)(d).
40 CFR 51.165(a)(3)(ii)(C)(1)	NR 408.06(7)(a), NR 408.06(7)(a)(1), and NR 408.06(7)(a)(4).
40 CFR 51.165(a)(3)(ii)(C)(2)	NR 408.06(7)(b).
40 CFR 51.165(a)(8)	NR 408.03(5).
40 CFR 51.165(a)(9)(ii)–(iv)	NR 408.06(4)(a)–(e), NR 408.06(5), and NR 408.05(2)(b).

B. Analysis of Wisconsin's NNSR Rules

For the following reasons, we are approving Wisconsin's certification that NR 408 is consistent with 40 CFR 51.165 and meets the requirements of CAA sections 110(a)(2), 172(c)(5), 173, 182(a)(4), and 182(b)(5) under the 2015 ozone standard.

1. Major Source Thresholds for Ozone—40 CFR 51.165(a)(1)(iv)(A)(1)(i)–(iv) and (2)

The major source thresholds for both volatile organic compounds (VOC) and nitrogen oxides (NO_X) (*i.e.,* ozone precursors) are defined in 40 CFR 51.165(a)(1)(iv)(A)(1)(i)–(iv) and (2). The applicable thresholds vary depending on the classification of the ozone nonattainment area. Different emissions thresholds apply for Marginal, Moderate, Serious, Severe and Extreme ozone nonattainment areas and for areas located in an ozone transport region (OTR).

Wisconsin has certified that the Federal requirements for major source thresholds for VOC and NO_X are addressed by NR 408.02(21). Under NR 408.02(21)(a), for an area designated as nonattainment for ozone, a major stationary source is a stationary source which emits or has the potential to emit VOC in an amount equal to or greater than (1) 100 tons per year in an area classified as marginal or moderate nonattainment for ozone (NR 408.02(21)(a)(1); (2) 50 tons per year of VOC in an area designated as serious nonattainment for ozone (NR 408.02(21)(a)(1)(b)); (3) 25 tons per year of VOC in an area designated as severe for ozone (NR 408.02(21)(a)(1)(d)); and (4) 10 tons per year of VOC in an area designated as extreme for ozone (NR 408.02(21)(a)(1)(e)). Under NR 408.02(21)(b), for an area designated as nonattainment for ozone, a major stationary source is a stationary source which emits or has the potential to emit NO_X in an amount equal to or greater than (1) 100 tons per year in an area classified as marginal or moderate nonattainment for ozone (NR 408.02(21)(b)(1)(a)); (2) 50 tons per year in an area classified as serious nonattainment for ozone (NR 408.02(21)(b)(2)); (3) 25 tons per year in an area classified as severe nonattainment for ozone (NR 408.02(21)(b)(3)); and (4) 10 tons per year in an area classified as extreme

[1] *See* 60 FR 3538.

[2] *See* 73 FR 76560.

nonattainment for ozone (NR 408.02(21)(b)(4)).

Wisconsin's thresholds are consistent with the Federal thresholds; therefore, we find that Wisconsin's NNSR provisions at NR 408.02(21) satisfy the requirements of 40 CFR 51.165(a)(1)(iv)(A)(1)(i)–(iv) and (2).

2. Change Constitutes Major Source by Itself—40 CFR 51.165(a)(1)(iv)(A)(3)

Under 40 CFR 51.165(a)(1)(iv)(A)(3), any physical change that would occur at a stationary source not qualifying as major stationary source becomes a major stationary source if the change would constitute a major stationary source by itself. Wisconsin has certified that the requirement is addressed by NR 408.02(21)(a)(3) which states that a major source includes any physical change that would occur at a stationary source not qualifying under subd. 1. or 2. as a major source, if the change would constitute a major source by itself. Wisconsin's provisions are consistent with Federal provisions; therefore, we find that the Wisconsin SIP at NR 408.02(21)(a)(3) satisfies the requirements of 40 CFR 51.165(a)(1)(iv)(A)(3).

3. Significant Net Emissions Increase of NO_X

Under 40 CFR 51.165(a)(1)(v)(E), any significant net emissions increase of NO_X is considered significant for ozone. Wisconsin has certified that this requirement is addressed by NR 408.02(20)(c), which provides that any significant net emissions increase of NO_X is considered significant for ozone in addition to any separate requirements for nitrogen oxides. Wisconsin's provisions at NR 408.02(20)(c) are consistent with the Federal requirements at 40 CFR 51.165(a)(1)(v)(E); therefore, we find that NR 408.02(20)(c) satisfies the requirements of 40 CFR 51. 165(a)(1)(v)(E).

4. Any Emissions Change in an Extreme Area Triggers NNSR—40 CFR 51.165(a)(1)(v)(F)

Under 40 CFR 51.165(a)(1)(v)(F), any physical change in, or change in the method of operation of, a major stationary source of VOC that results in any increase in emissions of VOC from any discrete operation, emissions unit, or other pollutant emitting activity at the source shall be considered a significant net emissions increase and a major modification for ozone, if the major stationary source is located in an extreme ozone nonattainment are that is subject to CAA title 1, part D, subpart 2. Wisconsin has certified that this requirement is addressed by NR 408.02(20)(a). NR 408.02(20)(a) provides that any physical change, or change in the method of operation of a major source of VOCs located in an extreme nonattainment area for ozone which results in any increase in emissions of VOCs from any discrete operation, emissions unit or other pollutant emitting activity at the source shall be considered a major modification for ozone. Wisconsin's provision at NR 408.02(20)(a) is consistent with the Federal requirements of 40 CFR 51.165(a)(1)(v)(F); therefore, we find that NR 408.02(20)(a) satisfies the requirements of 40 CFR 51.165(a)(1)(v)(F).[3]

5. Significant Emission Rates for VOC and NO_X

Under 40 CFR 51.165(a)(1)(x)(A), (B) and (E), the significant emission rate for ozone is 40 tons per year of VOC or NO_X, except that the significant emission rate in serious or severe nonattainment areas shall be 25 tons per year. Under 40 CFR 51.165(a)(1)(x)(E), any increase in actual emissions of VOC from any emissions unit at a major stationary source of VOC located in an extreme ozone nonattainment area shall be considered a significant net emissions increase.

Wisconsin has certified that NR 408.02(32)(a), (c), (d) and (f) satisfy these requirements. NR 408.02(32)(a) defines significant emission rates for NO_X of 40 tons per year and for ozone of 40 tons per year of VOC. NR 408.02(32)(c) defines significant for serious and severe ozone nonattainment areas as 25 tons per year of VOC. NR 408.02(32)(d) states that any increase in VOC emissions at a major source of VOC in an extreme ozone nonattainment area is considered significant. NR 408.02(32)(f) states that for purposes of applying NR 408.03(5) (major NSR applicability) to major sources of NO_X located in ozone nonattainment areas, the significant emission rates and other requirements for VOC shall apply to NO_X emissions. These provisions satisfy the requirements of 40 CFR 51.165(a)(1)(x)(A)–(C) and (E) with respect to VOC emissions. While the significant emission rate for ozone in NR 408.02(32)(a) does not specifically include NO_X, Wisconsin has certified that other provisions ensure NO_X would also be subject to the 40 tons per year significance rate for ozone. NR 408.03(2) provides that the NNSR requirements shall apply to any new source or major modification that is major for the pollutant, or precursor of the pollutant, for which the area is designated as nonattainment. Therefore, a major modification of NO_X in an ozone nonattainment area would trigger NNSR requirements for ozone. EPA finds that NR 408.02(32)(a), (c), (d) and (f) in conjunction with NR 408.03(2) satisfy the requirements of 40 CFR 51.165(a)(1)(x)(A)–(C) and (E).

6. Provisions for Emissions Reduction Credits—40 CFR 51.165(a)(3)(ii)(C)(1)–(2)

Under 40 CFR 51.165(a)(3)(ii)(C)(1) and (2), to be considered creditable, emission reductions achieved by shutting down an existing emission unit or curtailing production or operating hours must be surplus, permanent, quantifiable, and federally enforceable. Shutdowns or curtailments must have occurred after the last day of the base year for the SIP planning process. Reviewing authorities may choose to consider a prior shutdown or curtailment to have occurred after the last day of the base year if the projected emissions inventory used to develop the attainment demonstration explicitly includes emissions from the previously shutdown or curtailed emissions units, but in no event may credit be granted for shutdowns that occurred prior to August 7, 1977. Shutdown or curtailment reductions occurring before the last day of the base year for the SIP planning process may also be generally credited if the shutdown or curtailment occurred on or after the date the construction permit application is filed or if the applicant can establish that the proposed new emissions unit is a replacement for the shutdown or curtailed emission unit and the emission reductions that result are surplus, permanent, quantifiable, and federally enforceable. Wisconsin certified that the requirements of NR 408.06(7)(a), NR 408.06(7)(a)(1), NR 408.06(7)(a)(4), and NR 408.06(7)(b) satisfy these requirements.

NR 408.06(7)(a) states that emissions reductions achieved by shutting down an existing source or curtailing production or operating hours below baseline levels may be generally credited if (1) The reductions are surplus, permanent, quantifiable and federally enforceable . . . (4) The shutdown or curtailment occurs on or after the date specified for this purpose in the state implementation plan, and if the date specified is on or after the date of the most recent emissions inventory used in the plan's demonstration of attainment. The Wisconsin Department of Natural Resources (WDNR) may consider a prior shutdown or

[3] Wisconsin does not currently have any extreme ozone nonattainment areas.

curtailment to have occurred after the date of its most recent emissions inventory, if the inventory explicitly includes as current existing emissions the emissions from the previously shut down or curtailed sources. However, no credit is available for shutdowns which occurred prior to August 7, 1977. NR 408.06(7)(b) states that the emission reductions described in par. (a) may be credited in the absence of an EPA approved SIP only if the shutdown or curtailment occurs on or after the date the construction permit application is filed or if the applicant can establish that the proposed new source is a replacement for the shut down or curtailed source, and the cutoff date provisions of par. (a)4. are observed. EPA finds these provisions to be consistent with the Federal requirements; therefore, we find that the provisions of NR 408.06(7)(a), NR 408.06(7)(a)(1), NR 408.06(7)(a)(4) and NR 408.06(7)(b) satisfy the requirements of 40 CFR 51.165(a)(3)(ii)(C)(1) and (2).

7. Requirements for VOC Apply to NO_X

Under 40 CFR 51.165(a)(8), all requirements applicable to major stationary sources and major modifications of VOC shall apply to NO_X except where the Administrator has granted a NO_X waiver applying the standards set forth under CAA section 182(f) and the waiver continues to apply. Wisconsin has certified that these Federal requirements are satisfied by NR 408.03(5). NR 408.03(5) states the requirements of sections NR 408.04 to 408.10 applicable to new major sources or major modifications of VOC shall apply to NO_X emissions from new major sources or major modifications of NO_X, except that the requirements do not apply if the Administrator determines, when the Administrator approves a plan, plan revision or petition under provisions of section 182(f) of the CAA, that the statutory requirements of section 182(f) do not apply. We find that NR 408.03(5) is consistent with the requirements of 40 CFR 51.165(a)(8); therefore, we find that the Wisconsin SIP satisfies the requirements of 40 CFR 51.165(a)(8).

8. Offset Ratios for VOC and NO_X

Under 40 CFR 51.165(a)(9)(ii)(A)–(E), the VOC offset ratios shall be 1.1:1 in marginal ozone nonattainment areas, 1.15:1 in moderate ozone nonattainment areas, 1.2:1 in serious ozone nonattainment areas, and 1.3:1 in severe ozone nonattainment areas, and 1.5:1 in extreme ozone nonattainment areas. NR 408.06(4) states that in meeting the requirements of sub. (3) for ozone nonattainment areas classified under section 182 of the CAA, the ratio of total actual emission reductions of VOCs, and NO_X, where applicable, to the net emissions increase for the same air contaminant class shall be as follows:

(a) In any rural transport or marginal nonattainment area for ozone: At least 1.1 to 1.

(b) In any moderate nonattainment area for ozone: At least 1.15 to 1.

(c) In any serious nonattainment area for ozone: At least 1.2 to 1.

(d) In any severe nonattainment area for ozone: At least 1.3 to 1.

(e) In any extreme nonattainment area for ozone: At least 1.5 to l.

The offset ratios for both VOC and NO_X are consistent with 40 CFR 51.165(a)(9)(ii)(A)–(E); therefore, we find that the requirements of NR 408.06(4) satisfy the requirements of 40 CFR 51.165(a)(9)(ii)(A)–(E).

40 CFR 51.165(a)(9)(iv) requires, for ozone nonattainment areas subject to CAA title 1, part D, subpart 1 but not subpart 2, an offset ratio of at least 1:1. All of the current ozone nonattainment areas in Wisconsin were designated pursuant to CAA title 1, part D, subpart 2, and so this requirement does not apply to Wisconsin at this time.

9. OTR Requirements

Wisconsin is not located in an OTR, and has certified as such. Wisconsin is not required to include the OTR provisions set forth in 40 CFR 51.165(a)(1)(iv)(A)(1)(ii), 40 CFR 51.165(a)(1)(iv)(A)(2)(ii), 40 CFR 51.165(a)(1)(v)(E), 40 CFR 51.165(a)(1)(x)(C), 40 CFR 51.165(a)(8), and 40 CFR 51.165(a)(9)(iii) in the SIP until such time that EPA publishes rules that establish Wisconsin as part of the OTR.

10. Anti-Backsliding Provisions—40 CFR 51.165(a)(12)

Anti-backsliding provisions are designed to ensure that for existing ozone nonattainment areas that are designated nonattainment for a revised and more stringent ozone NAAQS, (1) there is protection against degradation of air quality (*i.e.,* the areas do not ''backslide''), (2) the areas continue to make progress toward attainment of the new, more stringent NAAQS, and (3) there is consistency with the ozone NAAQS implementation framework outlined in CAA title 1, part D, subpart 2. *See* 78 FR 34211 (June 6, 2013). As part of the SIP Requirements Rule, EPA revoked the 1997 NAAQS for all purposes and established anti-backsliding requirements for areas that remained designated nonattainment for the revoked NAAQS. *See* 80 FR 12265 (March 6, 2015) and 40 CFR 51.165(a)(12). Under 40 CFR 51.165(a)(12), the anti-backsliding requirements at 40 CFR 51.1105 apply in any area designated nonattainment for the 2008 ozone NAAQS and designated nonattainment for the 1997 ozone NAAQS on April 6, 2015. The anti-backsliding requirements apply to Sheboygan County, which was designated as a moderate ozone nonattainment area for the 1997 ozone NAAQS. Anti-backsliding requirements are addressed in documents issued by the WDNR pursuant to state statute 285.23(2), and are included as part of a separate SIP action.

II. What action is EPA taking?

EPA is approving Wisconsin's July 27, 2021, SIP revision addressing the NNSR requirements of the 2015 ozone NAAQS. EPA has concluded that Wisconsin's submission fulfills the 40 CFR 51.1314 revision requirement, meets the requirements of CAA sections 110 and 172 and the minimum SIP requirements of 40 CFR 51.165. We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant March 21, 2022 without further notice unless we receive relevant adverse written comments by February 18, 2022. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective March 21, 2022.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices,

provided that they meet the criteria of the CAA. Accordingly, this 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 CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 21, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: January 12, 2022.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends title 40 CFR part 52 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.*

■ 2. Section 52.2585 is amended by adding paragraph (pp) to read as follows:

§ 52.2585 Control Strategy: Ozone.

* * * * *

(pp) *NNSR certification.* Approval—On July 27, 2021, Wisconsin submitted a SIP revision certifying that the existing SIP-approved nonattainment new source review regulations fully satisfy the nonattainment new source review requirements for all areas not attaining the 2015 Ozone NAAQS.

[FR Doc. 2022–00935 Filed 1–18–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2020–0554; FRL–9297–01–R3]

Approval and Promulgation of Air Quality Implementation Plan; Delaware; Emissions Statement Certification for the 2015 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision formally submitted by the Delaware Department of Natural Resources and Environmental Control (DNREC). The revision provides Delaware's certification that its existing emissions statement program satisfies the emissions statement requirements of the Clean Air Act (CAA) for the 2015 ozone national ambient air quality standard (NAAQS). EPA is approving Delaware's emissions statement program certification for the 2015 ozone NAAQS as a SIP revision in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on February 18, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2020–0554. 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.

FOR FURTHER INFORMATION CONTACT: Serena Nichols, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2053. Ms. Nichols can also be reached via electronic mail at *Nichols.Serena@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 31, 2021 (86 FR 16683), EPA published a notice of proposed rulemaking (NPRM) that proposed approval of Delaware's certification that its emissions statement regulation meets the emissions statement requirement of Section 182(a)(3)(B) of the CAA for the 2015 ozone NAAQS. The formal SIP revision was submitted by the State of Delaware, through DNREC, on August 3, 2020.

II. Summary of SIP Revision and EPA Analysis

On August 3, 2020, Delaware, through DNREC, submitted as a formal SIP revision, a statement certifying that Delaware's existing SIP-approved emissions statement program satisfies the emissions statements requirements for the 2015 ozone NAAQS and is at least as stringent as the requirements of CAA Section 182(a)(3)(B). The provisions that implement Delaware's emissions statements program codified at 7 DE Administrative Code 1117 Section 7.0 and were approved by EPA into the Delaware SIP on April 29, 1996 (61 FR 7415, February 28, 1996). See 40 Code of Federal Regulations (CFR) 52.420(c). Table 1 in this document, summarizes Delaware's emissions statements provisions and the corresponding CAA Section 182(a)(3)(B) requirements.

TABLE 1—DELAWARE EMISSIONS STATEMENTS PROVISIONS AND CAA SECTION 182(a)(3)(B) REQUIREMENTS

CAA section 182(a)(3)(B) [1] requirement	7 DE administrative code 1117 section 7.0 requirement
182(a)(3)(B)(i)—For marginal nonattainment areas, the State shall submit a SIP revision to require that the owner or operator of each stationary source of nitrogen oxides (NO_X) or volatile organic compounds (VOCs) provide the State with a statement for classes or categories of sources showing the actual emissions of NO_X and VOC from that source.	7 DE Admin Code 1117 Section 7.1—Emissions statements requirements apply to all stationary sources located in an ozone nonattainment area that emit NO_X or VOC. This would include marginal and above non-attainment areas. 7 DE Admin Code 1117 Section 7.2—Emissions statements are required to include the following information: Source identification information, operating data, actual emissions data, control equipment information, and process rate information.
182(a)(3)(B)(i)—Emissions statements are required to be submitted annually.	7 DE Admin Code 1117 Section 7.3—subject sources must submit to DNREC their annual emissions statements by April 30 for the preceding calendar year. DNREC may require more frequent emissions statements if required by EPA or if more frequent analysis of data is necessary to implement the requirements of Title 7, Chapter 60. Environmental Control of the Delaware Code (7 Del.C. Chapter 60).
182(a)(3)(B)(i)—Emissions statements shall contain a certification that the information contained in the statement is accurate to the best knowledge of the individual certifying the statement.	7 DE Admin Code 1117 Section 7.2—Each emissions statement shall include a certification of the data to ensure that the information contained in the statement is accurate to the best knowledge of the individual certifying the statement, who shall be an official of the facility and will take legal responsibility for the emissions statement's accuracy.
182(a)(3)(B)(ii)—The State may waive the requirements for emissions statements for any class or category of stationary sources which emit less than 25 tons per year (tpy) of NO_X or VOCs if the State provides an inventory of emissions from such class or category of sources as required by CAA Section 172 and 182.	7 DE Admin Code 1117 Section 7.1—DNREC may, with EPA approval, waive the emissions statements requirements for classes or categories of stationary sources with facility-wide actual emissions of less than 25 tpy of NO_X or VOCs if the class or category is included in the base year and periodic ozone SIP emission inventories.

[1] Section 182 of the CAA sets out a graduated control program for ozone nonattainment areas. Section 182(a) sets out requirements applicable in marginal ozone nonattainment areas, which are also applicable by Sections 182(b), (c), (d), and (e) to all other ozone nonattainment areas. See 2015 memorandum titled ''Emission Statement Requirement Under 8-hour Ozone NAAQS Implementation,'' available online at *https://www.epa.gov/sites/production/files/2015-07/documents/8hourozone_naaqs_031406.pdf,* Docket ID: EPA–R03–OAR–2020–0554.

EPA has determined that the SIP-approved provisions under 7 DE Administrative Code 1117 Section 7.0 satisfy the requirements of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS. Therefore, EPA is proposing to approve, as a SIP revision, the State of Delaware's, August 3, 2020 emissions statements certification for the 2015 ozone NAAQS as approvable under CAA Section 182(a)(3)(B).

Other specific requirements of DNREC's June 4, 2020 submittal and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here. Two supportive public comments were received on the NPRM.

III. Final Action

EPA is approving, as a SIP revision, the State of Delaware's emissions statement certification for the 2015 ozone NAAQS as approvable under CAA Section 182(a)(3)(B). Delaware's emissions statement certification certifies that Delaware's existing SIP-approved emissions statement program under 7 DE Administrative Code 1117 Section 7.0 satisfies the requirements of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS.

IV. Statutory and Executive Order Reviews

A. General Requirements

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

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

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 21, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action approving Delaware's emissions statement certification for the 2015 ozone NAAQS 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: January 10, 2022.

Diana Esher,

Acting Regional Administrator, Region III.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 I—Delaware

■ 2. In § 52.420, the table in paragraph (e) is amended by adding an entry for ''Emissions Statement Certification for the 2015 Ozone National Ambient Air Quality Standard'' at the end of the table to read as follows:

§ 52.420 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Emissions Statement Certification for the 2015 Ozone National Ambient Air Quality Standard.	Delaware's portion of the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE 2015 ozone NAAQS nonattainment area (*i.e.,* New Castle County).	8/3/20	1/19/2022, [insert **Federal Register** citation].	Certification that Delaware's SIP-approved regulations under 7 DE Administrative Code 1117 Section 7.0 meet the emissions statements requirements of CAA Section 182(a)(3)(B) for the 2008 ozone NAAQS.

[FR Doc. 2022–00976 Filed 1–18–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0045; FRL–9331–01–OCSPP]

Ethaboxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethaboxam in or on *Brassica,* leafy greens, subgroup 4–16B and Vegetable, *Brassica,* head and stem, group 5–16. The Interregional Research Project Number 4 (IR–4) requested these tolerance actions under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 19, 2022. Objections and requests for hearings must be received on or before March 21, 2022, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0045, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

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

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other relatedinformation?

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0045 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before March 21, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0045, by one of the following methods:

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 22, 2021 (86 FR 15162) (FRL–10021–44) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8871) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to establish tolerances in 40 CFR 180.622 for residues of the fungicide ethaboxam, (*N*-(cyano-2-thienylmethyl)-4-ethyl-2-(ethylamino)-5-thiazolecarboxamide) in or on *Brassica,* leafy greens, subgroup 4–16B at 7 parts per million (ppm) and Vegetable, *Brassica,* head and stem, group 5–16 at 3 ppm. That document referenced a summary of the petition prepared by IR–4, the petitioner, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . . ''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ethaboxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ethaboxam follows.

In an effort to streamline its publications in the **Federal Register**,

EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for ethaboxam, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to ethaboxam and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings that remain unchanged as described further in this rulemaking.

Toxicological profile. For a discussion of the Toxicological Profile of ethaboxam, see Unit III.A. of the ethaboxam tolerance rulemaking published in the **Federal Register** of August 3, 2017 (82 FR 36086) (FRL–9961–69).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for ethaboxam used for human risk assessment, see Unit III.B. of the August 3, 2017 ethaboxam tolerance rulemaking.

Exposure assessment. Much of the exposure assessment remains unchanged from the previous rulemaking, although the exposure assessment has been updated to include the petitioned-for tolerances based on the same previous assumptions of tolerance level residues and 100 percent crop treated (PCT). Additionally, the estimated drinking water concentration is the same as that used in the previous assessment (7.4 ppb) for the chronic assessment (the only dietary assessment needed). There are no residential uses for ethaboxam, therefore no short- or intermediate-term exposure is expected. For a description of the previous approach to and assumptions for the exposure assessment, please reference Unit III.C. of the August 3, 2017 rulemaking.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the August 3, 2017 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and Determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute endpoint attributable to a single dose exposure was not identified; therefore, an acute dietary risk assessment was not conducted. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 39% of the cPAD for children 1 to 2 years old, the group with the highest estimated exposure. As the chronic dietary endpoint and dose are protective of potential cancer effects, ethaboxam is not expected to pose a dietary or aggregate cancer risk of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to ethaboxam residues. More detailed information on this action can be found in the document entitled, ''Ethaboxam. Human Health Risk Assessment for the Proposed New Uses on *Brassica* Head and Stem Vegetable Crop Group 5–16 and *Brassica* Leafy Greens Crop Subgroup 4–16B'' by going to the docket established by this action, EPA–HQ–OPP–2021–0045.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the August 3, 2017 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

Codex does not have established MRLs for ethaboxam in commodities that are members of subgroup 4–16B or group 5–16.

V. Conclusion

Therefore, tolerances are established for residues of ethaboxam in or on *Brassica,* leafy greens, subgroup 4–16B at 7 ppm and Vegetable, *Brassica,* head and stem, group 5–16 at 3 ppm.

VI. Statutory and Executive Order Reviews

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

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has

determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: December 29, 2021.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Amend § 180.622, by adding in alphabetical order to table 1 to paragraph (a) the entries ''*Brassica,* leafy greens, subgroup 4–16B'' and ''Vegetable, *Brassica,* head and stem, group 5–16'' to read as follows:

§ 180.622 Ethaboxam; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B	7
* * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	3
* * * * *	

[FR Doc. 2022–00854 Filed 1–18–22; 8:45 am]

BILLING CODE 6560–50–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 1230 and 2554

RIN 3045–AA82

Annual Civil Monetary Penalties Inflation Adjustment

AGENCY: Corporation for National and Community Service.

ACTION: Final rule.

SUMMARY: The Corporation for National and Community Service (operating as AmeriCorps) is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalties under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Act) and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective January 19, 2022.

FOR FURTHER INFORMATION CONTACT: Kiara Rhodes, Office of General Counsel, at *PublicComments@cns.gov* or at 202–937–6965.

SUPPLEMENTARY INFORMATION:

I. Background

AmeriCorps, the operating name for Corporation for National and Community Service, is a Federal agency that engages millions of Americans in service. AmeriCorps members and AmeriCorps Seniors volunteers serve directly with nonprofit organizations to tackle our Nation's most pressing challenges. For more information, visit *americorps.gov.*

AmeriCorps has two civil monetary penalties in its regulations. A civil monetary penalty under the Act is a penalty, fine, or other sanction that: (1) Is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by Federal law; and (2) is assessed or enforced by an agency pursuant to Federal law; and (3) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. (*See* 28 U.S.C. 2461 note). A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the ''Act'') requires agencies to adjust their civil monetary penalties for inflation annually. This rule updates AmeriCorps' two civil penalties for inflation.

II. Method of Calculation

The inflation adjustment for each applicable civil monetary penalty is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October of the year in which the amount of each civil money penalty was most recently established or modified. *See* December 15, 2021, OMB Memo for the Heads of Executive Departments and Agencies, M–22–07, *Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.* The cost-of-living adjustment multiplier for 2022, based on the CPI–U for the month of October 2021, not seasonally adjusted, is 1.06222.

The agency identified two civil penalties in its regulations: (1) The penalty associated with Restrictions on Lobbying (45 CFR 1230.400) and (2) the penalty associated with the Program Fraud Civil Remedies Act (45 CFR 2554.1):

- The civil monetary penalties related to Restrictions on Lobbying (45 CFR 1230.400) range from $20,732 to $207,313. Using the 2022 multiplier, the new range of possible civil monetary penalties is from $22,022 to $220,212.
- The Program Fraud Civil Remedies Act of 1986 (45 CFR 2554.1) civil monetary penalty has an upper limit of $11,803. Using the 2022 multiplier, the new upper limit of the civil monetary penalty is $12,537.

III. Summary of Final Rule

This final rule adjusts the civil monetary penalty amounts related to Restrictions on Lobbying (45 CFR 1230.400) and the Program Fraud Civil Remedies Act of 1986 (45 CFR 2554.1). The range of civil monetary penalties related to Restrictions on Lobbying increase from ''$20,732 to $207,313'' to ''$22,022 to $220,212.'' The civil monetary penalties for the Program Fraud Civil Remedies Act of 1986

increase from ''up to $11,803'' to ''up to $12,537.''

IV. Regulatory Procedures

A. Determination of Good Cause for Publication Without Notice and Comment and With an Immediate Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553) provides that, when an agency for good cause finds that notice and public comment procedures are impracticable, unnecessary, or contrary to the public interest, then the agency may issue a rule without providing notice and an opportunity for prior public comment. The agency finds that there is good cause to except this rule from the public notice and comment provisions of the APA in this case. Because the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires the agency to update its regulations based on a prescribed formula, the agency has no discretion in the nature or amount of the change to the civil monetary penalties to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for public comment on this rule prior to promulgation. Thus, providing for notice and public comment is impracticable and unnecessary. Additionally, it would not be possible to meet the deadlines imposed by the Act if we were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and publish a final rule. Therefore, notice and comment for these proscribed updates is impracticable and unnecessary.

Furthermore, the agency finds under section 553(d)(3) of the APA that good cause exists to make this final rule effective immediately upon publication in the **Federal Register**. In the Act, Congress expressly required Federal agencies to publish annual inflation adjustments to civil penalties in the **Federal Register** by January 15 of each year, notwithstanding section 553 of the APA. Under the statutory framework and OMB guidance, the new penalty levels take effect immediately upon the effective date of the adjustment. The statutory deadline does not allow time to delay this rule's effective date beyond publication. Moreover, an effective date after January 15 would delay application of the new penalty levels, contrary to Congress's intent.

Accordingly, we are issuing the annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**.

B. Review Under Procedural Statutes and Executive Orders

The agency has determined that making technical changes to the amount of civil monetary penalties in its regulations does not trigger any requirements under procedural statutes and Executive orders that govern rulemaking procedures.

List of Subjects

45 CFR Part 1230

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 2554

Claims, Fraud, Organization and functions (Government agencies), Penalties.

For the reasons discussed in the preamble, under the authority of 42 U.S.C. 12651c(c), the Corporation for National and Community Service amends chapters XII and XXV, title 45 of the Code of Federal Regulations as follows:

PART 1230—NEW RESTRICTIONS ON LOBBYING

■ 1. The authority citation for part 1230 continues to read as follows:

Authority: Section 319, Pub. L. 101–121 (31 U.S.C. 1352); Pub. L. 93–113; 42 U.S.C. 4951, *et seq.;* 42 U.S.C. 5060.

§ 1230.400 [Amended]

■ 2. Amend § 1230.400 by:

■ a. In paragraphs (a), (b), and (e), removing ''$20,732'' and adding, in its place, ''$22,022'' each place it appears.

■ b. In paragraphs (a), (b), and (e), removing ''$207,313'' and adding, in its place, ''$220,212'' each place it appears.

Appendix A to Part 1230 [Amended]

■ 3. Amend appendix A to part 1230 by:

■ a. Removing ''$20,732'' and adding, in its place, ''$22,022'' each place it appears.

■ b. Removing ''$207,313'' and adding, in its place, ''$220,212'' each place it appears.

PART 2554—PROGRAM FRAUD CIVIL REMEDIES ACT REGULATIONS

■ 4. The authority citation for part 2554 continues to read as follows:

Authority: Pub. L. 99–509, Secs. 6101–6104, 100 Stat. 1874 (31 U.S.C. 3801–3812); 42 U.S.C. 12651c–12651d.

§ 2554.1 [Amended]

■ 5. Amend § 2554.1 by removing ''$11,803'' in paragraph (b) and adding, in its place, ''$12,537.''

Dated: January 13, 2022.

Fernando Laguarda,

General Counsel.

[FR Doc. 2022–00909 Filed 1–18–22; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

47 CFR Part 300

[Docket Number: 220112–0011]

RIN 0660–AA37

Manual of Regulations and Procedures for Federal Radio Frequency Management

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: The National Telecommunications and Information Administration (NTIA) is making certain changes to its regulations relating to the public availability of the Manual of Regulations and Procedures for Federal Radio Frequency Management (NTIA Manual). Specifically, NTIA is releasing a new edition of the NTIA Manual, with which Federal agencies must comply when requesting use of radio frequency spectrum.

DATES: *Effective:* January 19, 2022. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 18, 2022.

ADDRESSES: A reference copy of the NTIA Manual, including all revisions in effect, is available in the Office of Spectrum Management, 1401 Constitution Avenue NW, Room 1087, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Alan Frable, Office of Spectrum Management, at (202) 482–1670 or *afrable@ntia.gov.*

SUPPLEMENTARY INFORMATION:

Background

NTIA authorizes the U.S. Government's use of radio frequency spectrum. 47 U.S.C. 902(b)(2)(A). As part of this authority, NTIA developed the NTIA Manual to provide further guidance to applicable Federal agencies

on the use of the radio frequency spectrum for radio transmissions for telecommunications or for other purposes. The NTIA Manual is the compilation of policies and procedures that govern the use of the radio frequency spectrum by the U.S. Government. Federal Government agencies are required to follow these policies and procedures in their use of spectrum.

Part 300 of title 47 of the Code of Federal Regulations provides information about the process by which NTIA regularly revises the NTIA Manual and makes public this document and all revisions. Federal agencies are required to comply with the specifications in the NTIA Manual when requesting frequency assignments. *See* 47 U.S.C. 901 *et seq.,* Executive Order 12046 (March 27, 1978), 43 FR 13349, 3 CFR, 1978 Comp., p. 158.

This rule updates § 300.1 of title 47 of the Code of Federal Regulations to specify the edition of the NTIA Manual with which Federal agencies must comply when requesting frequency assignments. In particular, this rule amends the section by incorporating by reference the 2021 edition of the NTIA Manual. Upon the effective date of this rule, Federal agencies must comply with the requirements set forth in the 2021 edition of the NTIA Manual.

The NTIA Manual is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, by referring to Catalog Number 903–008–00000–8, and online at *https://www.ntia.gov/page/2011/manual-regulations-and-procedures-federal-radio-frequency-management-redbook.* A reference copy of the NTIA Manual, including all revisions in effect, is available in the Office of Spectrum Management, 1401 Constitution Avenue NW, Room 1087, Washington, DC 20230, by calling Alan Frable on (202) 482–1670.

Paperwork Reduction Act

This action does not contain collection of information requirements subject to the Paperwork Reduction Act (PRA). Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the Paperwork Reduction Act unless that collection displays a currently valid Office of Management and Budget (OMB) Control Number.

Executive Order 12866

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

Administrative Procedure Act/ Regulatory Flexibility Act

NTIA finds good cause under 5 U.S.C. 553(b)(3)(B) to waive prior notice and opportunity for public comment as it is unnecessary. This action amends the regulations to include the date of the most current edition of the NTIA Manual. These changes do not impact the rights or obligations to the public. The NTIA Manual applies only to Federal agencies. Because these changes impact only Federal agencies, NTIA finds it unnecessary to provide for the notice and comment requirements of 5 U.S.C. 553. NTIA finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for the reasons provided above. Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

Congressional Review Act

The NTIA Manual provides for policies and procedures for Federal agencies' use of spectrum. The NTIA Manual and the changes thereto do not substantially affect the rights or obligations of the public. As a result, this document is not a ''rule'' as defined by the Congressional Review Act, 5 U.S.C. 804(3)(C).

Executive Order 13132

This rule does not contain policies having federalism implications as that term is defined in Executive Order 13132.

Regulatory Text

List of Subjects in 47 CFR Part 300

Communications, Incorporation by reference, Radio.

For the reasons set forth in the preamble, NTIA amends 47 CFR part 300 as follows:

PART 300—MANUAL OF REGULATIONS AND PROCEDURES FOR FEDERAL RADIO FREQUENCY MANAGEMENT

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 47 U.S.C. 901 *et seq.,* Executive Order 12046 (March 27, 1978), 43 FR 13349, 3 CFR 1978 Comp., p. 158.

■ 2. Revise § 300.1(b) to read as follows:

§ 300.1 Incorporation by reference of the Manual of Regulations and Procedures for Federal Radio Frequency Management.

* * * * *

(b) The NTIA Manual is incorporated by reference into this section with approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at National Telecommunications and Information Administration, Office of Spectrum Management, 1401 Constitution Avenue NW, Room 1087, Washington, DC 20230, telephone: (202) 482–1670, and is available from the sources indicated in this paragraph (b). It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material, email *fr.inspection@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) Commerce Department, National Telecommunications and Information Administration, Office of Spectrum Management, 1401 Constitution Avenue NW, Washington, DC 20230. The NTIA Manual is available online at *https://www.ntia.gov/page/2011/manual-regulations-and-procedures-federal-radio-frequency-management-redbook* and from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, by referring to Catalog Number 903–008–00000–8.

(i) Manual of Regulations and Procedures for Federal Radio Frequency Management, 2021 Edition, dated January 2021.

(ii) [Reserved]

(2) [Reserved]

Dated: January 13, 2022.

Evelyn Remaley Hasch,

Associate Administrator, Office of Policy Analysis and Development, Performing the Non-Exclusive Duties and Functions of the Assistant Secretary of Commerce for Communications and Information, National Telecommunications and Information Administration.

[FR Doc. 2022–00927 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–60–P

Proposed Rules

Federal Register
Vol. 87, No. 12
Wednesday, January 19, 2022

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

DEPARTMENT OF ENERGY

10 CFR Parts 429, 430, and 431

[EERE–2019–BT–TP–0032]

RIN 1904–AE77

Energy Conservation Program: Test Procedure for Consumer Water Heaters and Residential-Duty Commercial Water Heaters

Correction

In proposed rule document 2021–27004, appearing on pages 1554–1614, in the issue of Tuesday, January 11, 2022, make the following correction:

On page 1554, in the first column, in the **DATES** section, in the second paragraph, in the second line: ''Tuesday, January 25, 2022,'' should read ''Thursday, January 27, 2022,''.

[FR Doc. C1–2021–27004 Filed 1–18–22; 8:45 am]

BILLING CODE 0099–10–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0535; FRL–9444–01–R5]

Air Plan Approval; Wisconsin; Wisconsin Nonattainment New Source Review Certification for the 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve, as a State Implementation Plan (SIP) revision, Wisconsin's certification that its SIP satisfies the nonattainment new source review (NNSR) requirements of the Clean Air Act (CAA) for the 2015 ozone National Ambient Air Quality Standard (NAAQS).

DATES: Comments must be received on or before February 18, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0535 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Rachel Rineheart, Environmental Engineer, Air Permit Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7017, *rineheart.rachel@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register,** EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives such comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: January 12, 2022.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2022–00934 Filed 1–18–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R05–OAR–2008–0138; EPA–R05–OAR–2011–0827; FRL–9397–01–R5]

Air Plan Approval; Indiana, Ohio; Definition of Chemical Process Plants Under State Prevention of Significant Deterioration Regulations and Operating Permit Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the State Implementation Plan (SIP) for Indiana and revisions to the Operating Permit Program for Ohio. The proposed revisions incorporate changes to the definition of ''chemical process plants'' under Indiana's Prevention of Significant Deterioration (PSD) regulations and under Ohio's operating permit program. EPA is also providing an opportunity for public comment on similar changes to the definition of ''major stationary source'' in Ohio's PSD regulations that were approved into the SIP on October 28, 2014. This opportunity is being provided because these revisions were not explicitly discussed in the corresponding **Federal Register** action. The changes to the state rules described below are approvable because they are consistent with EPA regulations governing state PSD and title V

programs and will not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171 of the Clean Air Act (CAA)), or any other applicable requirement of the CAA.

DATES: Comments must be received on or before February 18, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2011–0827 (Indiana) or EPA–R05–OAR–2008–0138 (Ohio) at *https://www.regulations.gov,* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For information regarding Indiana's PSD permit program: Michael Langman, Physical Scientist, Air Permit Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6867, *langman.michael@epa.gov.* For information regarding Ohio's title V operating permit or PSD permit programs: Mari González, Environmental Engineer, Air Permit Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6175, *gonzalez.mari@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

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

I. What is being addressed in this document?

EPA is proposing to approve revisions to a SIP submission received from Indiana on September 21, 2011. EPA is also proposing to approve revisions to the Ohio Title V Operating Permit Program and providing an opportunity for the public to provide comments on related revisions to Ohio's PSD regulations that were approved on October 28, 2014 (79 FR 64119). These revisions address changes made to EPA regulations that are reflected in EPA's final rule entitled ''Prevention of Significant Deterioration, Nonattainment New Source Review (NA NSR), and Title V: Treatment of Certain Ethanol Production Facilities Under the 'Major Emitting Facility' Definition'' (hereinafter referred to as the ''2007 Ethanol Rule'') as published in the **Federal Register** on May 1, 2007 (72 FR 24059). The 2007 Ethanol Rule amended the PSD definition of ''major stationary source'' in the Federal PSD regulations (40 CFR 51.166 paragraphs (b)(1)(i)(*a*), (b)(1)(iii)(*t*) and (i)(1)(ii)(*t*)) to exclude certain ethanol facilities from the ''chemical process plant'' source category. In doing so, it established the PSD major source threshold for ethanol production facilities at 250 tons per year (tpy) rather than 100 tpy. The 2007 Ethanol Rule also removes the requirement to include fugitive emissions when determining if an ethanol production facility is major for PSD and title V permitting.

On October 21, 2019, EPA responded to a petition for reconsideration of the 2007 Ethanol Rule, denying the petition with respect to the revisions of the PSD regulations reflected in that rule (as described in more detail below). EPA is now proposing to approve revisions to Indiana's SIP and Ohio's operating permit program that are based on a part of the 2007 Ethanol Rule.

II. Background

A. PSD Permitting Thresholds for Chemical Process Plants Prior to the 2007 Ethanol Rule

Under the CAA, there are two potential thresholds for determining whether a source is a major emitting facility that is potentially subject to the construction permitting requirements under the PSD program. One threshold is 100 tpy per pollutant, and the other is 250 tpy per pollutant. Section 169(1) of the CAA lists twenty-eight source categories that qualify as major emitting facilities if their emissions exceed the 100 tpy threshold. If the source does not fall within one of twenty-eight source categories listed in section 169, then the 250 tpy threshold is applicable.

One of the source categories in the list of twenty-eight source categories to which the 100 tpy threshold applies is chemical process plants. Since the Standard Industrial Classification (SIC) code for chemical process plants includes facilities primarily engaged in manufacturing ethanol fuel, the EPA and states had previously considered such facilities to be subject to the 100 tpy thresholds.

As a result of this classification, pursuant to the EPA regulations adopted under section 302(j) of the CAA, chemical process plants were also required to include fugitive emissions for determining the potential emissions of such sources. Thus, prior to promulgation of the 2007 Ethanol Rule, the classification of fuel and industrial ethanol facilities as chemical process plants had the effect of requiring these plants to include fugitive emissions of criteria pollutants when determining whether their emissions exceed the applicability thresholds for the PSD and non-attainment NSR permit programs.

B. Title V Permitting Thresholds for Chemical Process Plants Prior to the 2007 Ethanol Rule

The CAA also establishes requirements for determining applicability for the title V operating permit program. All title V major sources must obtain a title V permit. Section 501(2) of the CAA defines major source for the purposes of the title V program as a major source as defined by section 112 of the CAA or a major stationary source as defined in section 302 or part D of title I of the CAA. Under the general definition of ''major stationary source'' in section 302(j) of the CAA, the major source threshold for

any air pollutant is 100 tons per year. Under the NSR requirements of Part D of title I of the CAA, lower thresholds for major sources can apply dependent upon the pollutant and the severity of the nonattainment classification. Major source thresholds for hazardous air pollutants (HAP) under section 112 of the CAA are 10 tpy of a single HAP or 25 tpy for any combination of HAPs. A source with emissions that exceed one of these thresholds is required to obtain a title V operating permit.

Section 502 of the CAA and EPA regulations provide that sources that belong to one of 28 categories listed in 40 CFR 70.2 must include fugitive emissions in determining applicability. The list of 28 source categories may also be included in approved state operating permit regulations.

C. Ethanol Rule

On May 1, 2007, EPA published the 2007 Ethanol Rule in the **Federal Register** (72 FR 24060). This final rule amended the PSD and NA NSR regulations to exclude ethanol manufacturing facilities that produce ethanol by natural fermentation processes from the ''chemical process plants'' category under the regulatory definition of ''major stationary source.''

This change to the NSR regulations affected the threshold used to determine PSD applicability for these ethanol production facilities, clarifying that such facilities were subject to the 250 ton per year major source threshold. The 2007 Ethanol Rule also changed how fugitive emissions are considered for affected ethanol production facilities. Because they would no longer be considered as part of the ''chemical process plants'' category, ethanol facilities would no longer be required to include fugitive emissions when determining major source status under PSD, NA NSR, and Title V.

D. Petitions for Review and Reconsideration of the 2007 Ethanol Rule

On July 2, 2007, the National Resources Defense Council (NRDC) petitioned the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) to review the 2007 Ethanol Rule. On that same day, EPA received a petition for administrative reconsideration and request for stay of the 2007 Ethanol Rule from NRDC. On March 27, 2008, the EPA denied NRDC's 2007 administrative petition for reconsideration.

On March 2, 2009, EPA received a second petition for reconsideration and a request for stay from NRDC. In 2009, NRDC also filed a petition for judicial review challenging EPA's March 27, 2008, denial of NRDC's 2007 administrative petition in the D.C. Circuit. This challenge was consolidated with NRDC's challenge to the 2007 Ethanol Rule. In August of 2009, the D.C. Circuit granted a joint motion to hold the case in abeyance, and the case has remained in abeyance.

On October 21, 2019, EPA partially granted and partially denied NRDC's 2009 administrative petition for reconsideration. Specifically, EPA granted the request for reconsideration with regard to NRDC's claim that the 2007 Ethanol Rule did not appropriately address the CAA section 193 antibacksliding requirements for nonattainment areas.

III. What revisions to the Indiana SIP is EPA proposing to approve?

On September 21, 2011, EPA received a request from Indiana to revise its SIP. More specifically, Indiana requested EPA to approve its PSD rules at 326 Indiana Administrative Code (IAC) 2–2–1 and NA NSR program rules at 326 IAC 2–3–2 to exclude ethanol production facilities that produce ethanol by natural fermentation from the chemical process plant source category.

In this action, EPA is proposing to approve the revisions to Indiana's PSD program at 326 IAC 2–2–1 related to the 2007 Ethanol Rule. EPA is taking no action at this time on Indiana's request to revise its NA NSR program at 326 IAC 2–3–2. Although Indiana also amended its Title V program at 326 IAC 2–7, EPA is not taking action with respect to Indiana's Title V operating permit program because Indiana did not request such a revision.

Pursuant to 40 CFR part 51 appendix V section 1.2, Indiana's September 2011 SIP submission was deemed complete by operation of law on March 21, 2012, six months after receipt of the request. The submission includes a formal signed and dated letter requesting approval of the revision to Indiana's PSD rules, a copy of the actual regulation, evidence showing that the state followed all procedural requirements, evidence that public notice was given of the proposed change, and certification that public hearings were held. IDEM adopted the revised PSD rules on May 4, 2011, after receiving no comments during the public comment period. The revised PSD rules became effective on August 20, 2011.

The state rule submitted for approval revised the PSD definition of ''major stationary source'' at 326 IAC 2–2–1(ff) to exclude certain ethanol production facilities that produce ethanol by natural fermentation from the chemical process plant source category. As a result of this revision, an ethanol production facility is subject to the 250 tpy PSD major stationary source threshold and is no longer required to consider fugitive emissions when determining its PSD major stationary source applicability. The ethanol production plants excluded from the chemical process plant source category at 326 IAC 2–2–1(ff) are identified by NAICS codes—these codes are the same as those identified in the 2007 Ethanol Rule and as identified at 40 CFR 51.166(b)(1)(i)(*a*).

EPA is proposing to approve the 2011 changes to 326 IAC 2–2–1(ff) into the Indiana SIP. Because sources in NAICS codes 325193 and 312140 that produce ethanol by natural fermentation are being excluded from the chemical process plant source category, EPA has determined that the requested changes to Indiana's PSD rules are consistent with the current PSD requirements at 40 CFR 51.166. 40 CFR 51.166(b)(1)(i)(*a*) excludes ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140 from the chemical process plant source category.

EPA has determined that the proposed revision will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA as required by section 110(l) of the CAA. Our determination is based on an analysis of Indiana's ethanol production trends, existing ethanol production permit requirements and locations with respect to ambient air monitoring, Indiana's statewide emissions inventory, Indiana's air quality design value trends, and representative photochemical modeling results for ozone and secondary fine particulate ($PM_{2.5}$) formation. Our analysis is included in the docket for this rulemaking.

Our analysis shows that Indiana's existing ethanol production facilities contribute 2% or less of each criteria pollutant when compared to statewide facility emissions. Indiana's total ethanol production has increased since 2007 but the state's air quality has steadily improved in general. Photochemical modeling of hypothetical sources representative of ethanol production facilities shows that ozone formation as a result of oxides of nitrogen (NO_X) and volatile organic compounds (VOC) emissions and secondary $PM_{2.5}$ formation as a result of NO_X and sulfur dioxide (SO_2) emissions will not themselves cause or contribute

to a violation of the ozone or $PM_{2.5}$ National Ambient Air Quality Standard (NAAQS). In addition, the applicability of Federal and state requirements to ethanol production facilities in Indiana, such as New Source Performance Standards at 40 CFR part 60 and National Emission Standards for Hazardous Air Pollutants at 40 CFR parts 61 and 63, will remain unaffected by this action.

IV. What revisions are being proposed by EPA in Ohio?

On February 7, 2008, EPA received a request from Ohio EPA to revise its SIP. This submittal included changes to the definition of ''major stationary source'' under Ohio Administrative Code (OAC) chapters 3745–31–01 and 3745–77–01, which incorporate into Ohio regulations the changes EPA made to Federal PSD and title V regulations in the 2007 Ethanol Rule. The changes to the definition of ''major stationary source'' in the PSD regulations in OAC chapter 3745–31–01 were approved into the SIP on October 28, 2014, but these changes were not explicitly discussed in the final rulemaking action that was published in the **Federal Register** (79 FR 64119). Therefore, the technical support document (TSD) that is available as part of this docket was developed to demonstrate that the changes which were approved into Ohio's SIP in 2014 related to the Ethanol Rule and the corresponding title V revisions will not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable CAA requirement. In this action, EPA is proposing to approve the title V changes in OAC 3745–77–01 relating to the 2007 Ethanol Rule and providing an opportunity for public comment on those changes, as well as the changes to the PSD program in OAC 3745–31–01 relating to the 2007 Ethanol Rule that were approved into Ohio's SIP in 2014.

The changes to the PSD program that EPA approved in 2014 are revisions under the definition of ''major stationary source'' for stationary sources located in an attainment area that emit or have the potential to emit 100 tpy or more of any regulated NSR pollutant. Ethanol facilities that produce ethanol through natural fermentation were excluded from the definition of ''chemical process plants.''

EPA has determined that these changes are consistent with the current PSD requirements at 40 CFR 51.166 and that the 2014 revisions will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA. This determination is based on EPA's 110(l) analysis provided in the accompanying TSD for Ohio which includes ethanol production trends in the state, an analysis of air quality design value trends, an examination of Ohio's statewide emissions inventory, photochemical modeling for ozone and secondary $PM_{2.5}$ formation, maps of existing ethanol facilities and ambient air monitors, and existing ethanol facility permit requirements. The analysis demonstrates that emissions from ethanol production facilities account for less than 1.5% of total point source emissions for five criteria pollutants examined in Ohio. While ethanol production has steadily increased in Ohio since 2007, in general, air quality has improved throughout the state as demonstrated by the downward trend in design values for criteria pollutants. Photochemical modeling for ozone based on NO_X and VOC emissions and secondary $PM_{2.5}$ formation based on NO_X and SO_2 emissions from hypothetical ethanol sources demonstrates that that new ethanol sources and major modifications at existing sources would not likely cause a violation of the NAAQS. The analysis also includes a discussion of existing Federal requirements that limit emissions to which Ohio's ethanol facilities are subject.

The regulations that EPA approved under the PSD program and is proposing to approve under Ohio's title V program adopt language that is the same as or consistent with the language of EPA's 2007 Ethanol Rule. The state regulations that EPA is proposing to approve under the title V program similarly exclude production facilities that produce ethanol by natural fermentation from the ''chemical process plants'' category. These revisions clarify that an ethanol facility need not include fugitive emissions when determining major source applicability under title V.

EPA is proposing to approve the revision to the Ohio title V Operating Permit Program under the definition of ''Major source'' for a major stationary source of air pollutants that directly emits or has the potential to emit 100 tpy or more of any pollutants. EPA has determined that these changes are consistent with the current requirements for title V under 40 CFR part 70.

Based on the 110(l) analysis provided in the Ohio TSD that is available as part of this docket, EPA concludes that the changes which were approved into Ohio's PSD SIP in 2014 related to the Ethanol Rule and the corresponding title V revisions will not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable CAA requirement.

V. What action is EPA taking?

EPA is proposing to approve revisions to the Indiana SIP in 40 CFR 52.770. EPA is also proposing to approve revisions to the Ohio title V Operating Permit Program in 40 CFR 70 appendix A, and providing an opportunity for public comment on the 2014 revisions to the Ohio PSD SIP in 40 CFR 52.1870 related to the 2007 Ethanol Rule. The revisions that EPA is proposing to approve change the definition of ''major stationary source'' under Indiana's PSD regulations and Ohio's Operating Permit Program. EPA is not taking action on changes related to NA NSR in this action. This action would approve changes to the state regulations that establish that the PSD applicability threshold for certain ethanol plants is 250 tpy and remove the requirement to include fugitive emissions when determining if an ethanol plant is subject to major source requirements under PSD and the title V Operating Permit Programs. EPA has determined that these revisions are consistent with EPA's PSD and title V regulations and that approval of these revisions is consistent with the requirements of CAA section 110(l) and will not adversely impact air quality.

VI. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference for Indiana rule 326 IAC 2–2–1(ff), effective August 20, 2011. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission and state Title V program submissions that comply with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a); 42 U.S.C. 7661a(d); 40 CFR 70.1(c), 70.4(i). Thus, in reviewing SIP submissions and Title V program revision submissions, EPA's role is to approve state choices, provided that they meet the criteria of

the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

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

List of Subjects

40 CFR Part 52

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

40 CFR Part 70

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 6, 2022.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2022–00467 Filed 1–18–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 87, 1030, and 1031

[EPA–HQ–OAR–2019–0660; FRL–9354–02 OAR]

RIN 2060–AU69

Control of Air Pollution From Aircraft Engines: Emission Standards and Test Procedures; Rescheduling of Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; rescheduling of public hearing.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a virtual public hearing to be held on February 17, 2022, on its proposed rulemaking for particulate matter (PM) emission standards for aircraft engines, which was signed on December 17, 2021. This hearing is being rescheduled from the previous date of January 20, 2022.

DATES: EPA will hold a virtual public hearing on February 17, 2022. The hearing will begin at 1 p.m. Eastern Time (ET) and end when all parties who wish to speak have had an opportunity to do so. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

ADDRESSES: The public hearing will be held virtually. Additional information regarding the hearing appears below under the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Bryan Manning, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4832; email address: *manning.bryan@epa.gov.*

SUPPLEMENTARY INFORMATION: The Environmental Protection Agency (EPA) is proposing PM emission standards and test procedures applicable to certain classes of engines used by civil subsonic jet airplanes (those engines with rated output of greater than 26.7 kilonewtons (kN)). These proposed standards and test procedures are equivalent to the aircraft engine standards adopted by the United Nations' International Civil Aviation Organization (ICAO) in 2017 and 2020. The proposed rulemaking was signed on December 17, 2021, and it will be published separately in the **Federal Register**. The pre-publication version is available at *https://www.epa.gov/regulations-emissions-vehicles-and-engines/proposed-rule-control-air-pollution-aircraft-engines.*

Participation in virtual public hearing. Please note that EPA is deviating from its typical approach because the President has declared a national emergency. Because of current recommendations from the Centers for Disease Control and Prevention (CDC), as well as state and local orders for social distancing to limit the spread of COVID–19, EPA cannot hold in-person public meetings at this time.

EPA is also asking all hearing attendees to register for the hearing, even those who do not intend to provide testimony, by February 14, 2022. Information on how to register for the hearing can be found at *https://www.epa.gov/regulations-emissions-vehicles-and-engines/proposed-rule-control-air-pollution-aircraft-engines.* For those without internet access, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to register.

The last day to pre-register to speak at the hearing will be February 14, 2022. The virtual public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the proposal (the official version of which was signed on December 17, 2021 and a copy of which is available at *https://www.epa.gov/regulations-emissions-vehicles-and-engines/proposed-rule-control-air-pollution-aircraft-engines*). EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. EPA recommends submitting the text of your oral comments as written comments to the rulemaking Docket ID No. EPA–HQ–OAR–2019–

0660, which can be found at *https://www.regulations.gov.*

The hearing will begin at 1:00 p.m. Eastern Time (ET) and end when all parties who wish to speak have had an opportunity to do so. A five-minute time limit will be placed on all oral testimony.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/regulations-emissions-vehicles-and-engines/proposed-rule-control-air-pollution-aircraft-engines.* While EPA expects the hearing to go forward as set forth above, please monitor our website or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to determine if there are any updates. EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodations such as audio description, please pre-register for the hearing and describe your needs by February 14, 2022. EPA may not be able to arrange accommodations without advance notice.

How can I get copies of the proposed action and other related information? EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2019–0660, which can be found at *https://www.regulations.gov.* EPA has also developed a website for this proposed rule at *https://www.epa.gov/regulations-emissions-vehicles-and-engines/proposed-rule-control-air-pollution-aircraft-engines.* Please refer to the notice of proposed rulemaking for detailed information on accessing information related to the proposal.

William Charmley,

Director, Assessment and Standards Division, Office of Transportation and Air Quality.

[FR Doc. 2022–00997 Filed 1–14–22; 4:15 pm]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3355–RCN]

RIN 0938–AT55

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance; Extension of Timeline for Publication of Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Extension of timeline for publication of final rule.

SUMMARY: The Social Security Act (the Act) specifies that a Medicare final rule must be published no later than 3 years after the publication date of the proposed rule or interim final rule, as applicable, except under exceptional circumstances. In accordance with the Act, this document announces an extension of the timeline for publication of the final rule and includes a brief explanation of the justification for the variation.

DATES: As of January 18, 2022, the timeline for publication of the final rule to finalize the provisions of the proposed rule published on February 4, 2019 (84 FR 1536), is extended until February 4, 2023.

FOR FURTHER INFORMATION CONTACT: Sarah Bennett, CMS, (410) 786–3531 or Nancy Anderson, CDC, (404) 498–2741.

SUPPLEMENTARY INFORMATION: In the February 4, 2019, **Federal Register** (84 FR 1536), we published a proposed rule entitled ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance'', which would update proficiency testing (PT) regulations under the CLIA to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. This proposed rule would also make additional technical changes to PT referral regulations to more closely align with the CLIA statute.

Section 1871(a)(3)(B) of the Social Security Act (the Act) requires the Secretary to publish a Medicare final rule no later than 3 years after the publication date of the proposed rule or interim final rule, as applicable, except under exceptional circumstances. In such circumstances, the Secretary may vary the final rule publication timeline if the Secretary publishes a **Federal Register** notice of the different timeline, including a brief explanation of the justification for the variation, by no later than the previously established timeline. To meet the 3-year timeline, the final rule would have to be published by February 4, 2022. For the reasons discussed below, we are unable to publish the final rule by February 4, 2022. In accordance with section 1871(a)(3)(B) of the Act, this document announces an extension of the timeline for publication of the final rule by 1 year until February 4, 2023.

Since the COVID–19 public health emergency was effective January 27, 2020, we prioritized our efforts to issue appropriate regulatory flexibility provisions to increase access to reliable and accurate testing relevant to COVID–19, while minimizing unnecessary regulatory burdens. This redirection continues to require considerable focus and resources, especially to prioritize the publication of notices relevant to COVID–19 and to provide guidance to laboratories involved in COVID–19 testing. Therefore, we cannot meet the February 4, 2022 deadline. However, we intend to publish the final rule by February 4, 2023. Extension of the timeline to allow for issuing the final rule is critical as the release of the final rule is anticipated, and we expect stakeholders, including the laboratory community and others, will react positively to the changes to the CLIA regulations. The practice of laboratory medicine has changed significantly since the PT regulations were published in 1992. There are several clinically important analytes in common use today for which PT was not required in the 1992 rule. The laboratory community is aware of this and other gaps that will be addressed by this final rule. Stakeholders are actively requesting updates to the PT analytes, acceptance limits, and microbiology model and have frequently inquired about the status of the final rule since 2019. For these reasons and based on comments we received in response to the proposed rule, it is important to extend the timeline to issue this final rule to revise and update the CLIA PT regulations.

Karuna Seshasai,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2022–00932 Filed 1–18–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 220110–0008]

RIN 0648–BK77

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Amendment 53

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Amendment 53 to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (Gulf)(FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council)(Amendment 53). This proposed rule and Amendment 53 would modify the allocation of Gulf red grouper catch between the commercial and recreational sectors as well as revise sector annual catch limits (ACLs) and annual catch targets (ACTs). The purposes of this proposed rule and Amendment 53 are to revise the red grouper sector allocations using the best scientific information available and to modify the allowable harvest of red grouper based on results of the recent stock assessment.

DATES: Written comments must be received by February 18, 2022.

ADDRESSES: You may submit comments on the proposed rule identified by ''NOAA–NMFS–2021–0098'' by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov* and enter ''*NOAA–NMFS–2021–0098*'' in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit all written comments to Peter Hood, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of Amendment 53, which includes an environmental assessment, a fishery impact statement, a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review, and electronic copies of a minority report submitted by four Council members, may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/amendment-53-red-grouper-allocations-and-catch-levels.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *peter.hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Gulf reef fish fishery, which includes red grouper, under the FMP. The Council prepared the FMP and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the optimum yield from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

Unless otherwise noted, all weights in this proposed rule are in gutted weight.

Red grouper in the Gulf exclusive economic zone (EEZ) are found primarily in the eastern Gulf on offshore hard bottom areas and are managed as a single stock with commercial and recreational ACLs and ACTs. The allocation of the ACL between the commercial and recreational sectors is currently 76 percent commercial and 24 percent recreational and was set through Amendment 30B to the FMP in 2009 (74 FR 17603; April 16, 2009).

Commercial red grouper fishing is managed under the Grouper-Tilefish Individual Fishing Quota (IFQ) program, which began January 1, 2010 through Amendment 29 to the FMP (74 FR 44732; August 31, 2009, and 75 FR 9116; March 1, 2010). Under the IFQ program, the commercial red grouper quota is based on the commercial sector's red grouper ACT (commercial quota), and red grouper allocation is distributed on January 1 of each year to those who hold red grouper shares. Both red grouper and gag, another grouper species managed under the IFQ program, have a multi-use provision that allows a portion of the red grouper quota to be harvested under the gag allocation, and vice versa. The multi-use provision is based on the difference between the respective ACLs and ACTs.

The recreational red grouper harvest is managed with catch limits, in-season and post-season accountability measures (AMs), season and area closures, a minimum size limit, and a recreational bag limit. The in-season AM for red grouper requires NMFS to close the recreational sector for the remainder of the fishing year when red grouper landings reach or are projected to reach the recreational ACL. If recreational landings exceed the red grouper recreational ACL in a fishing year, the post-season AM requires NMFS to shorten the length of the following recreational fishing season by the amount necessary to ensure landings do not exceed the recreational ACT. If the red grouper stock is overfished, NMFS must also reduce the ACL and ACT by the amount of the recreational ACL overage in the prior year. The recreational red grouper AMs were implemented in 2012 (77 FR 6988; February 10, 2012) and were modified in 2013 (78 FR 6218; January 30, 2013).

In 2018, the Council received a recommendation from its Scientific and Statistical Committee (SSC) to reduce the red grouper commercial and recreational ACLs and ACTs, effective for the 2019 fishing year. This recommendation was based on an interim analysis conducted by the Southeast Fisheries Science Center (SEFSC). The Council also heard concerns from fishermen about the condition of the red grouper stock because commercial and recreational harvests were well below the respective quota and ACL. The SSC did not feel comfortable recommending a new acceptable biological catch based on the analysis but determined that the analysis did support recommending that the Council reduce the 2019 total ACL from 10.70 million lb (4.85 million kg) to 4.60 million lb (2.09 million kg). The Council noted the severe red tide conditions that occurred in the summer and fall of 2018 off the Florida west coast and decided to further reduce the total ACL to an amount equivalent to

the 2017 harvest of 4.16 million lb (1.89 million kg). The Council took action by initially requesting an emergency rule to reduce red grouper ACLs and ACTs (84 FR 22389, May 17, 2019), and then making the harvest reductions permanent in a subsequent framework action (84 FR 52036; October 1, 2019).

The Southeast Data, Assessment, and Review (SEDAR) 61 assessment was completed in September 2019, and used updated recreational catch and effort data from the Marine Recreational Information Program (MRIP) Access Point Angler Intercept Survey (APAIS) and Fishing Effort Survey (FES). MRIP began incorporating a new survey design for APAIS in 2013 and replaced the Coastal Household Telephone Survey (CHTS) with FES in 2018. Prior to the implementation of MRIP in 2008, recreational landings estimates were generated using the Marine Recreational Fisheries Statistics Survey (MRFSS). As explained in Amendment 53, total recreational fishing effort estimates generated from MRIP–FES are generally higher than both the MRFSS and MRIP CHTS estimates. For example, the current red grouper total ACL and recreational ACL in MRIP CHTS units are 4.16 million lb (1.89 million kg) and 1.00 million lb (0.45 million kg), respectively. In MRIP–FES units, that red grouper total ACL and recreational ACL would be an estimated 5.26 million lb (2.39 million kg) and 2.10 million lb (0.95 million kg), respectively. This difference is because MRIP–FES is designed to more accurately measure fishing activity, not because there was a sudden rise in fishing effort.

NMFS developed calibrations models to adjust historic effort estimates so that they can be compared to new estimates from MRIP–FES. The calibration methodologies are discussed in Section 1.1 of Amendment 53 as well as in the SEDAR 61 final report. In response to comments on the integrated draft environmental impact statement, NMFS added information to Section 1.1 and included links to the calibration peer reviews. However, this peer review information has been publicly available since the reviews were completed in 2017 and 2018. In addition, a publication titled ''Survey Design and Statistical Methods for Estimation of Recreational Fisheries Catch and Effort'' has been available since 2018, and can be found at *https://media.fisheries.noaa.gov/2021-09/MRIP-Survey-Design-and-Statistical-Methods-2021-09-15.pdf.* This publication explains the different recreational fishing surveys and the time-series calibration methods.

The SEDAR 61 assessment concluded that the Gulf red grouper stock is not overfished and overfishing is not occurring, but that as of 2017, the stock remained below the spawning stock biomass (SSB) at 30 percent of the spawning potential ratio (SPR), where SPR is the ratio of SSB to its unfished state. Based on the results of SEDAR 61, the Council's SSC recommended an overfishing limit (OFL) of 5.35 million lb (2.43 million kg) and an acceptable biological catch (ABC) of 4.90 million lb (2.22 million kg). Because these catch levels are in MRIP–FES units, the recommended ABC appears to be larger than the current total ACL of 4.16 million lb (1.89 million kg), but would actually result in a decrease in allowable harvest when compared to the 5.26 million lb (2.39 million kg) MRIP–FES equivalent. In addition, these catch level recommendations assumed status quo sector allocations for red grouper, which were based in part on 1986–2005 landings estimates generated by MRFSS. As explained in Amendment 53, retaining the current allocation would increase the commercial ACL but substantially decrease the recreational ACL when comparing like units. Therefore, the Council requested that the SSC review alternative catch level projections based on sector allocation alternatives that used MRIP–FES data and several time series (1986–2005, 1986–2009, and 1986–2018). The SSC reviewed these alternative sector allocation scenarios, affirmed that the SEDAR 61 (2019) assessment, which included MRIP–FES recreational landings, represented the best scientific information available, and provided alternative catch level recommendations based on the allocation alternatives.

The commercial-recreational allocation impacts the catch level projections produced by the assessment. As more of the total ACL is allocated to the recreational sector, the proportion of recreational discards increases. Recreational discard mortality rates are assumed to be less than commercial discard mortality rates but the magnitude of recreational discards is considerably greater than commercial discards. Generally, a fish caught and released by a recreational fishermen has a greater likelihood of survival than by a commercial fishermen because of how and where they fish. However, because of the much higher numbers of red grouper that are released by the recreational sector vs the commercial sector, the total number of discards that die from the recreational fishing exceeds those from the commercial fishing. This results in additional mortality for the stock and a lower projected annual yield, which means a lower OFL, ABC, and total ACL. However, this is not due to any change in how the recreational sector prosecutes the fishery but occurs because MRIP–FES estimates higher levels of fishing effort, and consequently a greater number of fish being caught, which includes discards and the associated mortality of discarding fish.

In Amendment 53, the Council considered several allocation alternatives: Maintaining the current allocation, maintaining the current commercial ACL and allocating the remaining pounds to the recreational sector, and using the various time series reviewed by the SSC to adjust the allocation to reflect the most recent understanding of historical landings. The Council decided to adjust the allocation using the same years used to set the current allocation in Amendment 30B to the FMP (1986–2005). The Council determined that this would best represent the historic landings for the years used in Amendment 30B while accounting for the change from MRFSS data to MRIP–FES data. Because the MRIP–FES landings estimates are greater than the previous estimates of recreational landings estimates, the commercial-recreational allocation would shift from 76 percent and 24 percent, respectively, to 59.3 percent and 40.7 percent, respectively. Based on the results of SEDAR 61 and using the proposed allocation of 59.3 percent commercial and 40.7 percent recreational, the Council's SSC recommended an OFL of 4.66 million lb (2.11 million kg) and an ABC of 4.26 million lb (1.93 million kg). The total ACL is equal to the ABC.

Management Measures Contained in This Proposed Rule

If implemented, this proposed rule would revise the sector ACLs and ACTs for the Gulf red grouper stock.

Annual Catch Limits and Annual Catch Targets

The current commercial ACL and ACT are 3.16 million lb (1.43 million kg) and 3.00 million lb (1.36 million kg), respectively. The current recreational ACL and ACT are 1.00 million lb (0.45 million kg) and 0.92 million lb (0.42 million kg) in MRIP CHTS units, respectively. In MRIP FES units, the current recreational ACL and ACT are estimated to be 2.10 million lb (0.95 million kg) and 1.93 million lb (0.88 million kg), respectively.

As explained previously, the ABC associated with the preferred allocation is 4.26 million lb (1.93 million kg) and the total ACL is equal to the ABC.

Applying the allocation selected by the Council in Amendment 53 to the total ACL results in a 2.53 million lb (1.15 million kg) commercial ACL and a 1.73 million lb (0.78 million kg) recreational ACL in MRIP FES units.

The Council did not apply the ACL/ACT Control Rule to set the commercial buffer between the ACL and ACT. Normally, a sector managed using an IFQ program without a commercial quota overage during its reference period (as was the case for the reference period 2016–2019) would yield a 0 percent buffer from the control rule. Instead, in Amendment 53, the Council decided to continue using a buffer of 5 percent between the commercial ACL and ACT to allow red grouper and gag share categories in the IFQ program to have a multi-use provision that allows a portion of the red grouper quota to be harvested under the gag multi-use allocation, and vice versa. Applying the 5 percent buffer to the proposed commercial ACL of 2.53 million lb (1.15 million kg) yields a commercial ACT of 2.40 million lb (1.09 million kg).

The Council did apply the ACL/ACT Control Rule to set the recreational sector buffer between the ACL and ACT. Using 2016–2019 MRIP FES landings data in the control rule produced a buffer of 9 percent, one percentage point greater than the current buffer. Applying this 9 percent buffer to the proposed recreational ACL of 1.73 million lb (0.78 million kg) generated a recreational ACT of 1.57 million lb (0.71 million kg) in MRIP FES units.

Minority Report

A minority report signed by four Council members raises several objections to the preferred allocation in Amendment 53, including allegations that the preferred allocation violates several provisions of the Magnuson-Stevens Act. These issues were also raised in public comments on the draft environmental impact statement, which is integrated into Amendment 53. Responses to those comments are included in Appendix J of Amendment 53. Consistent with those responses, NMFS has determined that the proposed rule is consistent with the relevant provisions of the Magnuson-Stevens Act. Any final rule will respond to comments on the proposed rule received by NMFS during the comment period, as well as the issues raised in the Council's minority report.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with Amendment 53, the Reef Fish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. The Magnuson-Stevens Act provides the legal basis for this proposed rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting and record-keeping requirements are introduced by this proposed rule. This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

NMFS prepared an initial regulatory flexibility analysis (IRFA) for this proposed rule, as required by section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of this proposed rule, why it is being considered, and the purposes of this proposed rule are contained in the preamble and in the **SUMMARY** section of the preamble. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The objective of this proposed rule is to use the best scientific information available to establish Gulf red grouper sector allocations, ACLs, and ACTs, thereby ensuring that the sector ACLs accurately reflect the commercial and recreational sectors' historical participation and the recreational ACL is consistent with data used to monitor recreational landings and trigger AMs. All monetary estimates in the following analysis are in 2019 dollars.

Amendment 53 would revise the sector allocations of the total ACL for Gulf red grouper from 76 percent for the commercial sector and 24 percent for the recreational sector to 59.3 percent for the commercial sector and 40.7 percent for the recreational sector. The current OFL, ABC, and total ACL are 14.16 million lb (6.42 million kg), 13.92 million lb (6.31 million kg), and 4.16 million lb (1.89 million kg), respectively. The recreational portion of these values are based on MRIP–CHTS data. Amendment 53 would change the OFL and ABC to 4.66 million lb (2.11 million kg) and 4.26 million lb (1.93 million kg), consistent with the results of the most recent stock assessment and the recommendations of the Council's SSC, and would set the total ACL equal to the ABC of 4.26 million lb (1.93 million kg). The recreational portion of these values are based on MRIP–FES data. Applying the new sector allocations would reduce the commercial ACL from 3.16 million lb (1.43 million kg) to 2.53 million lb (1.15 million kg) and the recreational ACL from 2.10 million lb (0.95 million kg) in MRIP–FES units, or 1.00 million lb (0.45 million kg) in MRIP–CHTS units, to 1.73 million lb (0.78 million kg) in MRIP–FES units. This proposed rule and Amendment 53 would retain the current 5 percent buffer between the commercial ACL and ACT (quota), resulting in a reduction of the commercial ACT (quota) from 3.00 million lb (1.36 million kg) to 2.40 million lb (1.09 million kg). However, it would increase the buffer between the recreational ACL and ACT from 8 percent to 9 percent, and thereby reduce the recreational ACT from 1.59 million lb (0.72 million kg) to 1.57 million lb (0.71 million kg) given the proposed reduction in the recreational ACL. As a result, this proposed rule is expected to directly regulate commercial fishing businesses that possess Gulf red grouper shares in the grouper-tilefish IFQ program and for-hire fishing businesses that target red grouper.

The commercial red grouper quota is allocated annually based on the percentage of red grouper shares in each IFQ account (*e.g.,* if an account possesses 1 percent of the red grouper shares and the commercial quota is 1.00 million lb (0.45 million kg), then that account would receive 10,000 lb (4,536 kg) of commercial red grouper quota). Although it is common for a single IFQ account with red grouper shares to be held by a single business, some businesses have multiple IFQ accounts with red grouper shares. As of February 19, 2020, 495 IFQ accounts held red grouper shares. These accounts and red grouper shares were owned by 436 businesses. Thus, it is assumed this proposed rule would directly regulate 436 commercial fishing businesses.

A valid charter-headboat (for-hire) Gulf reef fish vessel permit is required to legally harvest red grouper in the Gulf. NMFS does not possess complete ownership data regarding businesses that hold charter-headboat (for-hire) Gulf reef fish vessel permits, and thus potentially harvest red grouper. Therefore, it is not currently feasible to accurately determine affiliations between vessels and the businesses that own them. As a result, for purposes of this analysis, it is assumed each for-hire vessel is independently owned by a single business, which is expected to result in an overestimate of the actual number of for-hire fishing businesses directly regulated by this proposed rule.

NMFS also does not have data indicating how many for-hire vessels

actually harvest Gulf red grouper in a given year. However, in 2019, there were 1,277 vessels with valid charter-headboat Gulf reef fish vessel permits. Of these 1,277 vessels, 90 vessels are used primarily for commercial fishing purposes and thus are not considered for-hire fishing businesses in this analysis. Further, Gulf red grouper is only targeted and almost entirely harvested in waters off the west coast of Florida. Of the 1,277 vessels with valid charter-headboat Gulf reef fish vessel permits, 799 were homeported in Florida. Of these permitted vessels, 60 are primarily used for commercial fishing rather than for-hire fishing purposes and thus are not considered for-hire fishing businesses. In addition, 48 of these permitted vessels are considered headboats. Headboats take a relatively large, diverse set of anglers to harvest a diverse range of species on a trip, and therefore do not typically target a particular species. Therefore, it is assumed that no headboat trips would be canceled, and thus no headboats would be directly affected as a result of this proposed rule. However, charter vessels often target red grouper. Of the 799 vessels with valid charter-headboat Gulf reef fish vessel permits that are homeported in Florida, 691 vessels are charter vessels. A recent study reported that 76 percent of charter vessels with valid charter-headboat permits in the Gulf were active in 2017 (*i.e.,* 24 percent were not fishing). A charter vessel would only be directly regulated by this proposed rule if it is fishing. Given this information, our best estimate of the number of charter vessels that are likely to harvest Gulf red grouper in a given year is 525, and thus this proposed rule is estimated to directly regulate 525 for-hire fishing businesses.

For RFA purposes, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (50 CFR 200.2). A business primarily involved in the commercial fishing industry is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts (revenue) are not in excess of $11 million for all of its affiliated operations worldwide. NMFS does not collect revenue data specific to commercial fishing businesses that have IFQ accounts; rather, revenue data are collected for commercial fishing vessels in general. It is not possible to assign revenues earned by commercial fishing vessels back to specific IFQ accounts and the businesses that possess them because quota is often transferred across many IFQ accounts before it is used by a vessel for harvesting purposes, and specific units of quota cannot be tracked. However, from 2014 through 2018, the maximum annual gross revenue earned by a single vessel was about $2.39 million, which occurred in 2015. The average gross revenue per vessel was about $143,000 in that year. By 2018, the maximum and average gross revenue per vessel had decreased to about $1.04 million and $96,000, respectively. Based on this information, all commercial fishing businesses directly regulated by this proposed rule are determined to be small entities for the purpose of this analysis.

For other industries, the Small Business Administration has established size standards for all major industry sectors in the U.S., including for-hire businesses (NAICS code 487210). A business primarily involved in for-hire fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has annual receipts (revenue) not in excess of $8 million for all its affiliated operations worldwide. The maximum annual gross revenue for a single headboat in the Gulf was about $1.38 million in 2017. On average, annual gross revenue for headboats in the Gulf is about three times greater than annual gross revenue for charter vessels, reflecting the fact that businesses that own charter vessels are typically smaller than businesses that own headboats. Based on this information, all for-hire fishing businesses directly regulated by this proposed rule are determined to be small businesses for the purpose of this analysis.

If implemented, NMFS expects this proposed rule to directly regulate 436 of the 532 businesses with IFQ accounts, or approximately 82 percent of those commercial fishing businesses. Further, NMFS expects this proposed rule to directly regulate 525 of the 1,187 for-hire fishing businesses valid charter/headboat permits in the Gulf reef fish fishery, or approximately 44 percent of those for-hire fishing businesses. NMFS has determined that, for the purpose of this analysis, all directly regulated commercial and for-hire fishing businesses are small entities. Based on this information, NMFS expects the proposed rule to affect a substantial number of small entities.

Because revenue and cost data are not collected for the commercial fishing businesses that are expected to be directly regulated by this proposed rule, direct estimates of their economic profits are not available. However, economic theory suggests that annual allocation (quota) prices should reflect expected annual economic profits, which allows economic profits to be estimated indirectly. Further, the 436 commercial fishing businesses that own red grouper shares, and therefore receive red grouper quota at the beginning of each calendar year, also own shares and receive quota in the other IFQ share categories *i.e.,* red snapper, gag, shallow-water grouper, deep-water grouper, and tilefish. These businesses earn economic profits because of their ownership of these shares as well their red grouper shares. However, economic profits are only realized if the quota allocated to these businesses with shares is actually used for harvesting purposes (*i.e.,* no economic profits will accrue unless the quota results in the production and sale of seafood). Because the average annual commercial landings of red grouper from 2014–2018 and the proposed red grouper commercial quota are almost identical, NMFS assumes that all of the red grouper commercial quota will be harvested in the foreseeable future. Similarly, because practically all of the commercial red snapper quota has been used for harvesting in recent years, NMFS assumes that all of the commercial red snapper quota allocated to these businesses will be harvested in the foreseeable future. However, based on 2015–2019 data, NMFS expects that only 84 percent of the deep-water grouper commercial quota, 50 percent of the gag commercial quota, 35 percent of the shallow-water grouper commercial quota, and 78 percent of the tilefish commercial quota allocated to these businesses will be used for harvesting in the foreseeable future. Given these quota utilization rates in combination with average annual allocation prices in 2019 and annual commercial quotas in 2020 by share category, total economic profits for commercial fishing businesses with red grouper shares are estimated to be at least $18.61 million. This estimate does not account for any economic profits that may accrue to commercial fishing businesses that own red grouper shares from the harvest of non-IFQ species. Such profits are likely to be small because harvest of IFQ species accounts for around 85 percent of commercial IFQ vessels' average annual gross revenue, and economic profits from the harvest of non-IFQ species tend to be much smaller than those from IFQ species. Given that there are 436 commercial fishing businesses that own red grouper shares, the average annual expected economic profit per

commercial fishing business is at least $42,700.

However, most of these economic profits (82 percent) are the result of owning red snapper shares. Only approximately $1.77 million (or 9.5 percent) of their economic profits are due to the ownership of red grouper shares. This proposed rule is only expected to affect economic profits from the ownership of red grouper shares. Specifically, the action that proposes to reduce the OFL, ABC, total ACL, and the commercial sector allocation of the total ACL results in a reduction of the red grouper commercial ACL from 3.16 million lb (1.43 million kg) to 2.53 million lb (1.15 million kg) and the commercial red grouper ACT (quota) from 3.00 million lb (1.36 million kg) to 2.40 million lb (1.09 million kg). Given an annual allocation price of $.59/lb in 2019 for red grouper, this reduction in the commercial red grouper quota is expected to reduce economic profits to these commercial fishing businesses by $354,000, or about $812 per business. Thus, economic profit is expected to be reduced by no more than 1.9 percent on average per commercial fishing business.

Based on the most recent information available, average annual profit is $26,514 per charter vessel. The action that modifies the sector allocations, OFL, ABC, and total ACL results in a reduction of the red grouper recreational ACL from 2.10 million lb (0.95 million kg) in MRIP–FES units to 1.73 million lb (0.78 million kg) in MRIP–FES units. The ACL reduction is expected to reduce the recreational season length by 12 days, and thereby cause the number of trips targeting red grouper on charter vessels to decrease by 665 angler trips. Net Cash Flow per Angler Trip (CFpA) is the best available estimate of profit per angler trip by charter vessels. CFpA on charter vessels is estimated to be $141 per angler trip. Thus, NMFS expects the estimated reduction in charter vessel profits from this action to be $93,723, or $179 per vessel.

The action that proposes to increase the buffer between the recreational ACL and recreational ACT from 8 percent to 9 percent would decrease the recreational ACT from 1.59 million lb (0.72 million kg) to 1.57 million lb (0.71 million kg). The ACT reduction is only germane if the recreational sector exceeds its ACL in the future, as that would trigger the post-season AM, causing the recreational sector to be constrained to the recreational ACT rather than the recreational ACL. Average annual landings in the recreational sector from 2016 through 2019 are greater than the proposed recreational ACL, and so it is possible that the post-season AM may be triggered, causing the recreational sector, including the for-hire component, to be constrained to the ACT. If the post-season AM is triggered, the additional reduction in the recreational season length caused by this action is estimated to be 4 days, which NMFS expects to cause the number of trips targeting red grouper on charter vessels to decrease by an additional 204 angler trips. Thus, if the post-season AM is triggered, NMFS estimates that the reduction in charter vessel profits would be $28,764, or $55 per vessel.

Based on the above, NMFS expects the total reduction in profits for charter vessels from this proposed rule to be no more than $122,487, or $234 per charter vessel. Thus, profit would potentially be reduced by approximately 0.9 percent on average per for-hire fishing business.

Five alternatives, including the status quo, were considered for the proposed action to set the sector allocations for red grouper at 59.3 percent for the commercial sector and 40.7 percent for the recreational sector, and set the OFL, ABC, total ACL, commercial ACL, and recreational ACL at 4.66 million lb (2.11 million kg), 4.26 million lb (1.93 million kg), 4.26 million lb (1.93 million kg), 2.53 million lb (1.15 million kg), and 1.73 million lb (0.78 million kg) in MRIP–FES units, respectively. The status quo alternative would have maintained the current sector allocations for red grouper at 76 percent for the commercial sector and 24 percent for the recreational sector, and maintained the OFL, ABC, total ACL, commercial ACL, and recreational ACL of 14.16 million lb (6.42 million kg), 13.92 million lb (6.31 million kg), 4.16 million lb (1.89 million kg), 3.16 million lb (1.43 million kg), and 1.00 million lb (0.45 million kg) in MRIP–CHTS units, respectively. In general, the status quo alternative was not selected because it is not based on the best scientific information available. More specifically, the status quo alternative would continue to use estimates based on MRIP–CHTS data rather than MRIP–FES data for the recreational sector, even though MRIP–FES data have been determined to be the best scientific information available for estimating and monitoring landings and effort in the recreational sector. The status quo alternative would have also set OFL and ABC above the values produced by the most recent stock assessment and recommended by the Council's SSC.

A second alternative would have maintained the current sector allocations for red grouper at 76 percent for the commercial sector and 24 percent for the recreational sector, and resulted in an OFL, ABC, total ACL, commercial ACL, and recreational ACL of 5.35 million lb (2.43 million kg), 4.90 million lb (2.22 million kg), 4.90 million lb (2.22 million kg), 3.72 million lb (1.69 million kg), and 1.18 million lb (0.54 million kg) in MRIP–FES units, respectively. This alternative was not selected as it would have resulted in considerably lower net economic benefits to the Nation compared to the proposed action. In addition, because of the conversion from MRIP–CHTS to MRIP–FES, the second alternative would have also effectively resulted in a significant reallocation of the total ACL from the recreational sector to the commercial sector, thereby causing a much larger, adverse proportional effect on the recreational sector relative to the commercial sector compared to the proposed action, which was not considered to be fair and equitable.

A third alternative would have set the sector allocations for red grouper at 68.7 percent for the commercial sector and 31.3 percent for the recreational sector, and resulted in an OFL, ABC, total ACL, commercial ACL, and recreational ACL of 5.03 million lb (2.28 million kg), 4.60 million lb (2.09 million kg), 4.60 million lb (2.09 million kg), 3.16 million lb (1.43 million kg), and 1.44 million lb (0.65 million kg) in MRIP–FES units, respectively. Similar to the second alternative, the third alternative was not selected as it would have resulted in considerably lower net economic benefits to the Nation compared to the proposed action. Further, the third alternative would have maintained the current commercial ACL despite the required reduction in the total ACL. While this would have resulted in no effects on the commercial sector, it would have also resulted in a reallocation of the total ACL from the recreational sector to the commercial sector and thereby caused large adverse effects on the recreational sector compared to the proposed action, which was not considered to be fair and equitable.

A fourth alternative would have set the sector allocations for red grouper at 60.5 percent for the commercial sector and 39.5 percent for the recreational sector, and resulted in an OFL, ABC, total ACL, commercial ACL, and recreational ACL of 4.70 million lb (2.13 million kg), 4.30 million lb (1.95 million kg), 4.30 million lb (1.95 million kg), 2.60 million lb (1.18 million kg), and 1.70 million lb (0.77 million kg) in MRIP–FES units, respectively. A fifth alternative would have set the sector allocations for red grouper at 59.7

percent for the commercial sector and 40.3 percent for the recreational sector, and resulted in an OFL, ABC, total ACL, commercial ACL, and recreational ACL of 4.67 million lb (2.12 million kg), 4.28 million lb (1.94 million kg), 4.28 million lb (1.94 million kg), 2.56 million lb (1.16 million kg), and 1.72 million lb (0.78 million kg) in MRIP–FES units, respectively. The fourth and fifth alternatives were not selected because they did not use the same time series of years as the original sector allocation and therefore would not as accurately reflect the historical participation of the recreational and commercial sectors in the fishery, which is contrary to the Council's objectives. These alternatives were also not selected as they resulted in slightly lower net economic benefits to the Nation compared to the proposed action.

Two alternatives, including the status quo, were considered for the proposed action to maintain the buffer between the commercial ACL and commercial ACT of 5 percent and increase the buffer between the recreational ACL and recreational ACT from 8 percent to 9 percent. The status quo alternative would have maintained the buffer between the commercial ACL and commercial ACT of 5 percent and maintained the buffer between the recreational ACL and recreational ACT of 8 percent. The status quo alternative was not selected because the current recreational buffer is based on MRFSS data, which are no longer used for quota monitoring because they are no longer the best scientific information available.

The second alternative would have reduced the commercial buffer from 5 percent to 0 percent and increased the recreational buffer from 8 percent to 9 percent. Both the red grouper and gag share categories in the commercial grouper-tilefish IFQ program have a multi-use provision that allows a portion of the red grouper quota to be harvested under the gag allocation, and a portion of the gag quota to be harvested under the red grouper allocation. Each year, the program assigns a portion of each shareholder's red grouper and gag's allocations to the multi-use allocation category. The intent of the multi-use provision is to provide for allocation if either gag or red grouper are landed as incidental catch. The second alternative was not selected because, based on recent data, the gag multi-use allocation would be zero. As a result, red grouper could not be landed with gag allocation, which is contrary to the purpose of the multi-use provision in the grouper-tilefish IFQ program.

List of Subjects in 50 CFR Part 622

Annual catch limit, Fisheries, Fishing, Gulf, Red grouper, Reef fish.

Dated: January 10, 2022.

Samuel D. Rauch, III

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

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.39, revise paragraph (a)(1)(iii)(C) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(iii) * * *

(C) *Red grouper*—2.40 million lb (1.09 million kg).

* * * * *

■ 3. In § 622.41, revise the last sentence of paragraph (e)(1) and revise paragraph (e)(2)(iv) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(e) * * *

(1) * * * The commercial ACL for red grouper, in gutted weight, is 2.53 million lb (1.15 million kg).

(2) * * *

(iv) The recreational ACL for red grouper, in gutted weight, is 1.73 million lb (0.78 million kg). The recreational ACT for red grouper, in gutted weight, is 1.57 million lb (0.71 million kg).

* * * * *

[FR Doc. 2022–00646 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 220111–0010]

RIN 0648–BK74

Pacific Island Fisheries; Pelagic Longline Gear and Operational Requirements

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to prohibit the use of wire leaders in the Hawaii deep-set longline fishery, and require the removal of fishing gear from any oceanic whitetip shark caught in all of the region's domestic longline fisheries. The proposed action is intended to increase post-hooking survival of oceanic whitetip sharks.

DATES: NMFS must receive comments by February 18, 2022.

ADDRESSES: You may submit comments on this proposed rule, identified by NOAA–NMFS–2021–0099, by either of the following methods:

- *Electronic Submission:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov* and enter NOAA–NMFS–2021–0099 in the Search box, click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Send written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: NMFS may not consider comments sent by any other method, to any other address or individual, or received after the end of the comment period. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

The Western Pacific Fishery Management Council (Council) and NMFS prepared a draft environmental

assessment (EA) and regulatory impact review that supports this proposed rule. The draft EA is available at *www.regulations.gov,* or from the Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, or *www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: David O'Brien, PIRO Sustainable Fisheries, 808–725–5038.

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Hawaii (shallow-set and deep-set), America Samoa, and general western Pacific longline fisheries under the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP) and implementing Federal regulations. These fisheries occasionally catch oceanic whitetip sharks (*Carcharhinus longimanus*), which NMFS listed as threatened under the Endangered Species Act on January 30, 2018 (83 FR 4153). To improve the survival of oceanic whitetip sharks caught unintentionally in the Hawaii deep-set fishery, this proposed rule would prohibit the use of steel wire line, known as wire leaders, within 1 meter of the hook. To improve the survival of oceanic whitetip sharks caught unintentionally in all of the region's longline fisheries, this proposed rule would also require fishermen to remove fishing gear from any oceanic whitetip shark caught, with limited exceptions related to safety and data collection. Prohibiting wire leaders may also result in reductions in adverse effects to other protected species.

Prior to 2021, most vessels in the Hawaii deep-set fishery used wire leaders in the terminal portion of the fishing line between the hook and a weight that must be placed within 1 meter of the hook (see 50 CFR 665.815(a)(1)). The weight is typically in the form of a swivel, and helps to sink the hook quickly to reduce interactions with seabirds.

The wire leader also reduces the risk of crew injuries resulting from ''fly backs.'' Fly backs may occur when retrieving fishing gear (hauling) if the line under tension parts, either by breaking or being bitten through, between the hook and the weighted swivel or is thrown from a fish. In these cases, the weighted swivel flies back toward the vessel at high speed and there have been documented severe injuries and deaths of crewmembers. The use of wire leaders between the hook and the weight reduces the chance that the leader would part and fly back toward the vessel when crew are hauling the gear.

Although they reduce fly backs, wire leaders reduce the chances that sharks may bite off the line and release themselves before the crew retrieve the gear. We expect sharks that release themselves before the gear is retrieved to have reduced mortality relative to sharks that are released after being brought to the vessel. In addition, wire leaders make it difficult to remove fishing gear from sharks or other protected species that are too large to bring on board the vessel to remove the gear. Because it is difficult to cut the wire leader from deck height, fishermen typically cut the line closer to the vessel than the weighted swivel. This practice leaves the hook, wire leader, weighted swivel, and some amount of monofilament fishing line (collectively, trailing gear) attached to a released animal. Long trailing gear reduces survivorship of sharks and other released animals. Because monofilament nylon leaders are easier to cut from deck height, they can facilitate removal of trailing gear below the weighted swivel and close to the hook when releasing animals that are too large to bring on board.

To reduce impacts on oceanic whitetip sharks in the Hawaii deep-set fishery, the Hawaii Longline Association (HLA) announced in late 2020 that its members, comprising more than 90 percent of the Hawaii deep-set longline fleet of approximately 146 active vessels, would voluntarily switch from wire to monofilament leaders. At its June 2021 meeting, the Council recommended that wire leaders be prohibited in the Hawaii deep-set fishery, along with the recommendation to remove trailing gear. These recommendations were intended to ensure that all fishermen in the fleet stop using wire leaders and minimize the amount of trailing gear on oceanic whitetip sharks. NMFS estimates that these proposed requirements would reduce mortality of oceanic whitetip sharks hooked in the Hawaii deep-set fishery by approximately 30 percent due to a combination of higher post-hooking survival via bite-offs and reductions in trailing gear remaining on released animals. This proposed action would be implemented in conjunction with HLA outreach to fishery participants and NMFS protected species workshops to address safety concerns associated with gear fly back.

Pursuant to the Council's recommendations, NMFS proposes to prohibit wire leaders within 1 meter of each hook on Hawaii deep-set vessels. NMFS also proposes to require vessel owners, operators and crew on vessels registered for use under any of the region's longline permits to release oceanic whitetip sharks with minimal trailing gear, with limited exceptions for safety and data collection. This proposed rule and any related handling guidelines would be consistent with Western and Central Pacific Fisheries Commission best handling practices for these sharks (see *https://www.wcpfc.int/doc/supplcmm-2010-07/best-handling-practices-safe-release-sharks-other-whale-sharks-and*), and NMFS regulations at 50 CFR 300.226.

NMFS will consider public comments on this proposed rule and will announce the final rule in the **Federal Register**. NMFS must receive comments on this proposed action by the date provided in the **DATES** heading. NMFS may not consider comments postmarked or otherwise transmitted after that date. Regardless of the final rule, all other existing management measures would continue to apply in the longline fisheries.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

Certification of Finding of No Significant Impact on Substantial Number of Small Entities

The Chief Counsel for Regulation for the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

The proposed action would prohibit the use of wire leaders in the Hawaii deep-set longline fishery, and would require the removal of fishing gear from any oceanic whitetip shark caught in all of the region's domestic longline fisheries (Hawaii deep-set and shallow-set, American Samoa, and others).

The action would apply to vessels with Hawaii longline limited entry permits (164) and American Samoa limited entry permits (60). There has been no longline fishing in Guam or the Northern Mariana Islands since 2011. In 2020, 146 vessels participated in the Hawaii deep-set longline fishery, with annual fleet revenues of $71.5 million and average annual per-vessel revenues of $489,730. In 2020, 14 vessels participated in the Hawaii shallow-set

fishery, with annual fleet revenues of $1.3 million and average annual per-vessel revenues of $92,357. In 2020, 11 vessels participated in the American Samoa fishery, with annual fleet revenues of $2.1 million, and average per-vessel revenues of $191,000.

NMFS listed oceanic whitetip sharks as threatened under the Endangered Species Act on January 30, 2018 (83 FR 4153). The proposed management measures are designed to improve post-hooking survival of oceanic whitetip sharks in the longline fisheries. In December 2020, the HLA announced that its members, comprising most of the Hawaii deep-set longline fleet, would voluntarily switch from wire leaders to monofilament leaders in 2021. This proposed action would encourage the entire Hawaii deep-set longline fleet to transition to monofilament leaders, currently the only viable alternative to wire. It would also require that all longline fishermen operating vessels under the FEP follow specific steps in removing trailing gear, as practicable, to further enhance post-hooking survival of oceanic whitetip sharks. These proposed requirements are expected to reduce mortality of oceanic whitetip sharks due to a combination of higher post-hooking survival via bite-offs and reductions in the length of trailing gear remaining on released animals.

Most vessels in the Hawaii deep-set longline fishery had, until recently, used wire leaders to prevent potential gear fly backs and associated injury from weighted branch lines required for this fishery as a seabird mitigation measure. With the prohibition on the use of wire leaders under the proposed action, longline vessels are most likely to transition to monofilament nylon as it is the most common alternative leader material in pelagic longline fisheries, although other non-metal leaders may be used. Some, if not most, vessels in the Hawaii deep-set longline fishery are anticipated to voluntarily transition from wire leaders to monofilament leaders in advance of the regulatory requirement, following HLA's announcement. As of November 2021, most Hawaii deep-set longline fishing vessels had transitioned to monofilament leaders with many more transitioning to its use when existing wire leaders need to be replaced in the normal course of operations.

Under the proposed action, Hawaii deep-set longline fishery participants will incur upfront costs associated with changing wire leaders to monofilament nylon. The estimated range in the initial costs of replacing an entire set of wire leaders with monofilament leaders can be found by multiplying the price of each monofilament leader ($0.06–$0.17, depending on brand) by the average number of hooks. This results in an estimated average one-time material cost (averaging 2,876 hooks per vessel in 2020) for a full set of monofilament nylon leaders of $173–$489 per vessel, or a total of $25,194 to $71,382 for the entire fleet. Many deep-set longline vessels have already transitioned to monofilament nylon leaders, and more have begun to transition to monofilament nylon leaders as part of their routine replacement of leader lines. As a result, the upfront costs of transitioning to monofilament leaders upon the implementation of proposed action will not be as high for many fishermen as presented here.

The proposed action may also influence ongoing costs for maintenance and repair of fishing gear. Monofilament leaders are more susceptible to damage, abrasion, breaking, and bite-offs, which would result in more frequent repairs and replacement of longline gear. However, monofilament nylon is less expensive than wire, which may help offset the immediate costs of implementing the proposed action over the longer term. The EA used 2020 effort data and results from a research study that estimated branch line repair rates to be higher for monofilament nylon leaders (19.8 percent) compared to wire leaders (14.4 percent) to estimate differential maintenance and repair costs. In 2020, the number of hooks deployed per trip averaged 36,314 and the number of hooks deployed throughout the year averaged 408,904 across all vessels. Based on these hook numbers, the cost of repairing monofilament leaders would average from $431–$1,222 per vessel per trip, compared to an average of $2,144–$2,719 per vessel per trip to repair wire leaders. Thus, the proposed action could result in an overall decrease in leader repair material costs ranging from $922 to $2,288 per trip, or an annual decrease in leader replacement costs ranging from $1,515,186 to $3,761,100 fleetwide (based on 1,644 deep-set trips in 2020).

Most vessels in the deep-set fishery had used wire leaders to prevent potential gear fly backs and associated injuries from the weighted branch lines (required to prevent seabird interactions). This proposed action would be implemented in conjunction with HLA outreach to fishery participants and NMFS protected species workshops to address safety concerns associated with gear fly back. One initiative involves the use of a simple reusable fly back prevention device. The cost of the materials for making one device is approximately $13, with one to two of these devices needed on board a vessel during any given fishing trip.

The proposed rule also would require fishermen to remove trailing gear from captured oceanic whitetip sharks. HLA will continue to work with NMFS and the Western Pacific Fishery Management Council to disseminate handling guidelines applicable to oceanic whitetip sharks (and other protected species) for safe release with as little trailing gear attached as possible.

While fishermen in all three fisheries remove trailing gear when they catch sharks as part of their normal operations, these additional handling requirements may slightly increase the time it takes to release these sharks. However, the rarity of interactions with these sharks suggests that any increase in handling time should have negligible impact on fishing operations.

The prohibition of wire leaders, and the resulting switch to monofilament leaders, could change the catch rates of some target and non-target species in the Hawaii deep-set fishery. We expect minor increases in bigeye tuna catch rates, and slightly lower catch rates for albacore, mahimahi, and skipjack tuna. These changes are likely to be minor, however, and may result in an overall net increase in revenues for the deep-set fishery.

NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. Based on available information, NMFS has determined that all vessels permitted federally under the FEP are small entities, *i.e.,* they are engaged in the business of fish harvesting (NAICS 114111), are independently owned or operated, are not dominant in their field of operation, and have annual gross receipts not in excess of $11 million. Even though this proposed action would apply to a substantial number of vessels, the implementation of this action would not result in significant adverse economic impact to individual vessels. The proposed action would potentially reduce adverse effects on threatened oceanic whitetip sharks and other protected species, as well as potentially

Hawaii deep-set longline fishermen with minor increases in catch rate for target bigeye tuna.

Under the proposed action, we do not expect the region's domestic longline fisheries to change substantially (*i.e.,* area fished, number of vessels and trips, number and depth of hooks, or deployment techniques). The proposed action does not duplicate, overlap, or conflict with other Federal rules and is not expected to have significant impact on small organizations or government jurisdictions. Furthermore, there would be little, if any, disproportionate adverse economic impacts from the proposed action based on gear type or relative vessel size. The proposed action also will not place a substantial number of small entities, or any segment of small entities, at a significant competitive disadvantage to large entities.

For the reasons above, NMFS does not expect the proposed action to have a significant economic impact on a substantial number of small entities. As such, an initial regulatory flexibility analysis is not required and none has been prepared.

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

This proposed rule does not contain a collection-of-information requirement and thus requires no review under the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 665

American Samoa, Endangered and threatened species, Fisheries, Fishing, Hawaii, Longline, Oceanic whitetip shark, Pacific Islands, Release requirements, Western Pacific.

Dated: January 12, 2022.

Samuel D. Rauch, III, Deputy Assistant Administrator for Regulatory

Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 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 § 665.800, revise the definition of ''Deep-set or Deep-setting'' to read as follows:

§ 665.800 Definitions.

* * * * *

Deep-set or Deep-setting means the deployment of longline gear in a manner consistent with all the following criteria: All float lines are at least 20 meters in length; a minimum of 15 branch lines are attached between any two floats (except basket-style longline gear which may have as few as 10 branch lines between any two floats); no metal wire line within 1 meter of the hook; and no light sticks are used. As used in this definition, ''float line'' means a line used to suspend the main longline beneath a float, and ''light stick'' means any type of light emitting device, including any fluorescent ''glow bead,'' chemical, or electrically-powered light that is affixed underwater to the longline gear.

* * * * *

■ 3. In § 665.802, add paragraphs (gg) and (hh) to read as follows:

§ 665.802 Prohibitions.

* * * * *

(gg) Use or have on board longline gear with metal wire line within 1 meter of the hook when operating a vessel registered for use under a longline permit issued under § 665.801(b) at any time during a trip for which notification to NMFS under § 665.803(a) indicated that deep-setting would be done, in violation of § 665.813(d).

(hh) Fail to handle and release an oceanic whitetip shark in accordance with the requirements set forth at § 665.811(a) when operating a vessel registered for use under any longline permit issued under § 665.801, in violation of § 665.811.

* * * * *

■ 4. Add § 665.811 to read as follows:

§ 665.811 Handling and release of oceanic whitetip sharks.

(a) The owner and operator of a vessel registered for use under any longline permit issued under § 665.801 must release any oceanic whitetip shark as soon as possible after the shark is caught and brought alongside the vessel, in accordance with § 300.226 of this title, and must take the following actions:

(1) Leave the animal in the water.

(2) Use a dehooker as defined in § 665.812(a)(7), or line clippers as defined in § 665.812(a)(5), to remove trailing gear from the animal.

(3) When using line clippers, cut the branch line as close to the hook as possible.

(b) Paragraph (a) of this section shall not apply if doing so would compromise the safety of any person, or if a NMFS observer collects, or requests assistance collecting, samples of oceanic whitetip shark, or if a WCPFC observer collects, or requests assistance collecting, samples of oceanic whitetip shark in the Convention Area, as defined in § 300.211 of this title and in accordance with § 300.226 of this title.

■ 5. In § 665.813, revise paragraph (d) to read as follows:

§ 665.813 Western Pacific longline fishing restrictions.

* * * * *

(d) A vessel registered for use under a Hawaii longline limited access permit may not have on board at any time during a trip for which notification to NMFS under § 665.803(a) indicated that deep-setting would be done, any float line less than 20 meters in length, longline gear with metal wire line within 1 meter of the hook, or any light stick. As used in this paragraph (d), ''float line'' means a line used to suspend the main longline beneath a float, and ''light stick'' means any type of light emitting device, including any fluorescent ''glow bead,'' chemical, or electrically powered light that is affixed underwater to the longline gear.

* * * * *

[FR Doc. 2022–00910 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 12
Wednesday, January 19, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2021–0004]

Proposed Revisions to the National Handbook of Conservation Practices for the Natural Resources Conservation Service

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of availability; request for comment.

SUMMARY: NRCS is giving notice that it intends to issue a series of revised conservation practice standards in the National Handbook of Conservation Practices (NHCP). NRCS is also giving the public an opportunity to provide comments on specified conservation practice standards in NHCP.

DATES: *Comment Date:* We will consider comments that we receive by February 18, 2022.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments through the:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and search for docket ID NRCS–2021–0004. Follow the instructions for submitting comments.
- *Mail, or Hand Delivery:* Mr. Clarence Prestwich, National Agricultural Engineer, Conservation Engineering Division, NRCS, USDA, 1400 Independence Avenue, South Building, Room 4636, Washington, DC 20250. In your comment, specify the docket ID NRCS–2021–0004.

All comments will be available on *https://www.regulations.gov.*

The copies of the proposed revised standards are available through *https://www.regulations.gov* by accessing Docket No. NRCS–2021–0004. Alternatively, the proposed revised standards can be downloaded or printed from *https://go.usa.gov/TXye.*

FOR FURTHER INFORMATION CONTACT: Mr. Clarence Prestwich; telephone: (202) 720–2972; or email: *clarence.prestwich@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

NRCS is planning to revise the conservation practice standards in the NHCP. This notice provides an overview of the planned changes and gives the public an opportunity to provide comments on the specific conservation practice standards that NRCS is changing.

NRCS State Conservationists who choose to adopt these practices in their States will incorporate these practices into the respective electronic Field Office Technical Guide. These practices may be used in conservation systems that treat highly erodible land (HEL) or on land determined to be a wetland. Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 requires NRCS to make available for public review and comment all proposed revisions to conservation practice standards used to carry out HEL and wetland provisions of the law.

Revisions to the National Handbook of Conservation Practices

The amount of the proposed changes varies considerably for each of the conservation practice standards addressed in this notice. To fully understand the proposed changes, individuals are encouraged to compare these changes with each standard's current version, which can be found at: *https://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/technical/cp/ncps/?cid=nrcs143_026849.*

NRCS is requesting comments on the following conservation practice standards:

- Conservation Cover (Code 327);
- Emergency Animal Mortality Management (Code 368);
- Fishpond Management (Code 399);
- Forest Farming (Code 379);
- Irrigation System, Surface and Subsurface (Code 443);
- Land Reclamation, Landslide Treatment (Code 453);
- Mine Shaft and Adit Closing (Code 457);
- Pond (Code 378);
- Residue and Tillage Management, No Till (Code 329);
- Residue and Tillage Management, Reduced Till (Code 345);
- Subsurface Drain (Code 606);
- Tree/Shrub Pruning (Code 660);
- Vertical Drain (Code 630).

The following are highlights of some of the proposed changes to each standard:

Conservation Cover (Code 327): Minor revisions were made for improved organization and for clarity. The second purpose (Reduce ground and surface water quality degradation by nutrients and surface water quality degradation by sediment) was split into two separate purposes that are clearer and more succinct (Reduce sediment transport to surface water and Reduce ground water and surface water quality degradation by nutrients). The last purpose (Improve soil health) was changed to specifically focus on a measurable metric (Maintain or increase soil organic matter (OM) content). The language associated with the additional criteria was incorporated into the General Criteria section. We added three additional purposes (Improve soil aggregate stability, Improve habitat for soil organisms, and Reduce compaction) with Criteria sections added for both the purposes of Improve habitat for soil organisms and Reduce compaction.

Emergency Animal Mortality Management (Code 368): One of the Emergency Animal Mortality Management purposes was separated into two purposes. The two new purposes now address surface water and ground water separately. Minor wording changes were made to the Criteria and Considerations sections for clarity and specificity. Changes were made to the Operation and Maintenance section to add specific items for burial and add more items to composting. New references were added to the References section.

Fishpond Management (Code 399): There were no major changes to this standard. The three purposes were combined into one. Three additional considerations were added regarding addition of submerged habitat, removal of accumulated debris or sediment, and use of biological and/or mechanical methods to control nuisance aquatic species. The References section was updated to delete outdated references and include new documents.

Forest Farming (Code 379): The practice name was changed from

''Multi-Story Cropping'' to Forest Farming to reflect technical and popular literature. Forest Farming also aligns with other federal agencies (USDA Forest Service, Agricultural Research Service), non-government organizations (Savanna Institute, National Association of State Foresters), technical assistance, and outreach efforts. Definition and purposes were restructured and expanded to align with the new name and resource concerns. Minor revisions were made for improved organization and for clarity to the Criteria, Considerations, Plans and specifications, Operation and Maintenance, and References sections.

Irrigation System, Surface and Subsurface (Code 443): Minor revisions were made for improved organization and for clarity. The Definition section was simplified to remove the extended list of example components described in the Criteria section. Maximum pipeline velocity was reduced from 7 feet per second (fps) to 5 fps to make it consistent with other NRCS conservation practice standards. We added the utility location responsibility statement.

Land Reclamation, Landslide Treatment (Code 453): Formatting and writing style were updated to meet current agency requirements resulting in minor revisions for clarity and readability. Relatively minor technical additions were included in the Criteria and Considerations sections. Lists of required items were added to the Plans and Specifications and Operation and Maintenance sections. References were updated.

Mine Shaft and Adit Closing (Code 457): Formatting and writing style were updated to meet current agency requirements resulting in minor revisions for clarity and readability. In the Criteria section, the Safety subsection was reorganized to emphasize testing and personnel entry requirements. New subsections entitled ''Bats and other wildlife'', ''Discharge'', and ''Monuments'' were added to provide new guidance. The Report subsection was moved to the Plans and Specifications section where the list was expanded.

Pond (Code 378): Minor revisions were made for improved organization and for clarity in response to the availability of new information. Minor revisions were made to Table 1 to keep the data within the scope of the practice standard. We added a utility location responsibility statement to the General Criteria section. Changes were made to the Criteria Applicable to Embankment Ponds section to Filter diaphragms for improved explanation. NRCS would welcome comments regarding use of anti-seep collars for this practice.

Residue and Tillage Management, No Till (Code 329): Minor revisions were made for improved organization and for clarity. We added additional purposes relating to Soil Health Resource Concerns. We added Additional criteria for the added purpose of Soil Health. We added additional wording to the Considerations section to clarify Soil Health management principles. We updated the Plans and Specifications and the References sections.

Residue and Tillage Management, Reduced Till (Code 345): We added additional purposes relating to Soil Health Resource Concerns. Minor revisions were made for improved organization and for clarity. We added additional criteria for the added purposes for Soil Health. We added additional wording to the Considerations section to clarify Soil Health management principles. We updated the References section.

Subsurface Drain (Code 606): Formatting and writing style were updated to meet current agency requirements. The definition was expanded to address ''soil water conditions,'' rather than just ''excess water.'' An additional purpose of addressing animal health and productivity due to adverse soil conditions was added. The Conditions Where Practice Applies section was revised to encompass ''adverse'' soil conditions, rather than specifically the ''wet'' condition. Wetland conservation has been elevated to the General Criteria subsection. Filter and envelope terminology has been revised to align with recently released NEH 650, Chapter 14, Drainage.

Tree/Shrub Pruning (Code 660): Purpose and Criteria sections were further refined. Criteria were adjusted to match changes in purposes. Considerations and Plans and Specifications sections were further refined. New references were added.

Vertical Drain (Code 630): There are no changes to the criteria and only minor wording changes have been made that do not change the meaning of the conservation practice standards.

Louis Aspey,

Associate Chief, Natural Resources Conservation Service.

[FR Doc. 2022–00853 Filed 1–18–22; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket No. RBS–21–Business–0030]

Notice of Funding Opportunity for the Rural Energy Pilot Grants Program (REPP) for Fiscal Year 2022

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service (Agency) announces the availability of up to $10 million in competitive grants awarded to Rural Energy Community Partnerships (RECP) to further develop renewable energy to help meet our nation's energy needs and combat climate change while prioritizing environmental justice, racial equity, and economic opportunity. Cost-share grants of up to 80 percent of total eligible project costs but not more than $2 million will be made available to assist eligible entities with planning, installing, equipping, and maintaining community scale distributed renewable energy technologies, systems and resources.

DATES: Prior to the submission of an application, the Agency requires prospective applicants to inform the Agency by submitting a letter of intent electronically by no later than 11:59 p.m. Eastern time, April 19, 2022, to be eligible for grant funding. A Guide and instructions for submitting the Required Letter of Intent are available on the Rural Energy Pilot Program website, under the To Apply tab, *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program*. Letters of Intent received prior to the deadline will be reviewed and afforded a response by the Agency. On or before May 19, 2022, the Agency will send a letter of response. Prospective applicants are invited to submit a complete application electronically no later than 11:59 p.m. Eastern time, July 18, 2022, to be eligible for grant funding. Please refer to Section IV., of this Notice for content and format of required letters of intent and complete applications.

Prospective applicants are encouraged to review the REPP website for instructions on registering their organization as early as possible in order to meet the electronic application deadline. Applications submitted after the deadline will not be accepted, are not eligible for funding under this Notice, and will not be considered.

ADDRESSES: This funding opportunity will be posted to *https://*

www.grants.gov. Potential applicants should review *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program,* for requirements for electronic submission. Applicants must submit their application electronically. Electronic submissions of applications will allow for the expeditious review of an applicant's proposal.

FOR FURTHER INFORMATION CONTACT: Anthony Crooks: telephone (202) 205–9322, email: *RuralEnergyPilotProgram@usda.gov.* Persons with disabilities that require alternative means for communication should contact the U.S. Department of Agriculture (USDA) Target Center at (202)720–2600 (voice).

SUPPLEMENTARY INFORMATION: The Agency encourages applicants to consider projects that will advance the following key priorities (more details available at *https://www.rd.usda.gov/priority-points*):

- Assisting rural communities recover economically from the impacts of the COVID–19 pandemic, particularly disadvantaged communities.
- Ensuring all rural residents have equitable access to Rural Development (RD) programs and benefits from RD funded projects.
- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

The Agency advises all interested parties that the applicant bears the burden in preparing and submitting an application in response to this Notice.

Overview

Federal Agency: Rural Business-Cooperative Service (RBCS).

Funding Opportunity Title: Rural Energy Pilot Grant Program (REPP).

Announcement Type: Notice of Funding Opportunity.

Assistance Listing Number: 10.379.

Funding Opportunity Number): RBCS–REPP–2021.

Dates: Letters of intent must be received as specified in the **DATES** section of this Notice, as a prerequisite to filing a complete application.

Applicants receiving a letter of encouragement must submit a complete application as specified in the **DATES** section of this Notice to be eligible for grant funding.

The application guide provides specific, detailed instructions for each item of a complete application. The Agency emphasizes the importance of including every item and strongly encourages applicants to follow the instructions carefully.

Hemp related projects: Please note that no assistance or funding from this grant can be provided to a hemp producer unless they have a valid license issued from an approved State, Tribal or Federal plan as defined by the Agriculture Improvement Act of 2018, Public Law 115–334. Verification of valid hemp licenses will occur at the time of award.

The Agency will neither solicit nor consider new scoring or eligibility information submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification on materials contained in the submitted application.

Items in Supplementary Information

I. Program Overview

A. Background

The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) authorized and appropriated $10 million to remain available until expended for the Secretary of Agriculture to carry out a pilot program to provide financial assistance for rural communities to further develop renewable energy. Prior to publishing this Notice, RBCS (the Agency) determined it to be in the public interest to solicit informal comments from the public and interested stakeholders to help develop options for the Rural Energy Pilot Program (REPP) to support the nation's critical energy needs to combat climate change while advancing environmental justice, racial equity, and economic opportunity through the development and deployment of distributed energy technologies, innovations, and solutions.

A Request for Information and Notice of Stakeholder Listening Session on a Rural Energy Pilot Program was published in the **Federal Register** (86 *FR* 16575) on March 30, 2021. Information received from the public was intended to inform the Agency as well as the private sector and other stakeholders with interest in and expertise relating to such an effort in order to build on prior investments and experience gained through past small-scale energy solutions, social justice reforms, and climate change mitigation programs.

Seventy-five (75) comments were submitted from the public which served to inform the Agency on an array of issues, including but not limited to: Program purposes, goals, metrics and standards; eligible applicants, participants and partners, including but not limited to: Communities, residences, industry, and commercial entities; eligible technologies, including but not limited to, generation, storage, microgrid controllers and transmission grids; potential impact of the pilot program and renewable energy systems on each of the following: environmental justice, racial equity, and economic opportunity; and options to measure and maximize the benefits of renewable energy systems for environmental justice, racial equity, and economic opportunity in rural areas.

Additionally, on May 13, 2021, the Agency convened a Federal Inter-Agency Task Force of experts with relevant knowledge, including technical experts from the Environmental Protection Agency, Department of Energy, National Renewable Energy Laboratory, Pacific Northwest National Laboratory, and the Appalachian Regional Commission to assist with the review of the public comments and provide recommendations for the guiding principles of this Notice.

B. Program Description

The purpose of the REPP is to provide financial assistance for rural communities to further develop renewable energy. Grants are awarded on a competitive basis.

Under the REPP, funds will be awarded to assist Rural Energy Community Partnerships (RECP) to establish and develop clean energy communities through the deployment of community-scale distributed energy technologies, innovations and solutions.

The maximum grant award amount per applicant is $2,000,000. Grant funds may be used to pay for up to 80 percent of eligible project costs directly related to:

- Commercially-available, community-based, community scale distributed renewable energy systems; and
- Community energy planning, capacity building, technical assistance, efficiency and weatherization (up to 20 percent of awarded funds per funding request).

In its application an RECP will describe its proposal to establish a clean energy community. A proposal may include purposes such as but are not limited to community energy planning, capacity building, and technical assistance, community efficiency and weatherization and the deployment, installation, or equipping of community-scale renewable energy technologies or systems. Applicants will

describe the goals and objectives to be achieved through RECP's efforts at the completion of REPP grant period. These objectives may include but are not limited to the ability to withstand disruptive events, economic and energy resilience, increased environmental justice, improved racial equity, expanded economic opportunity, and the stability or diversification of distributive energy resources.

Applicants will propose performance measures that express successes and challenges of meeting the RECP's goals and objectives and report its accomplishments during the grant period and provide annual outcome reports for three years after project completion. Performance measures may include but are not limited to renewable energy generation and energy efficiency/energy savings (measured in kilowatt hours), project sustainability and resilience measured by inclusion of institutional partners and continued commitment of project financing, and community benefits measured in terms of power purchase agreement/subscription income (in dollars per kilowatt hour), reduced greenhouse gas/carbon dioxide emissions (in metric tons of CO2 equivalence), reduced energy burdens (in percentage of household incomes), measured environmental justice, measured equity, measured economic opportunity, etc.

C. Definitions of Terms

Applicant. The lead applicant entity acting on behalf of a rural energy community partnership that is seeking a REPP grant. The lead applicant will enter into a financial assistance agreement with the Agency in order to receive the REPP grant funding and will be responsible to administer the REPP grant in accordance with said agreement. All rights, responsibilities, and the disposition thereof pertaining to ownership and control of any assets acquired by the partnership are presumed to reside with the Applicant unless otherwise specified in a fully executed partnership agreement.

Capacity building. The process by which individuals, communities and organizations obtain, improve and retain the skills, knowledge, tools, equipment and other resources needed to achieve long-term, sustainable success.

Center for Disease Control, CDC/ATSDR Social Vulnerability Index (CDC/ATSDR SVI). A tool that uses U.S. Census data to determine the social vulnerability of every census tract. ATSDR's Geospatial Research, Analysis & Services Program (GRASP) maintains the CDC/ATSDR SVI to help public health officials and local planners better prepare for and respond to emergency events like hurricanes, disease outbreaks, or exposure to dangerous chemicals. Documentation for all versions of the CDC/ATSDR SVI can be found on the CDC Data & Documentation Download page.

Center for Disease Control, Socially Vulnerable Community. A community determined to be socially vulnerable as per the CDC/ATSDR Social Vulnerability Index (CDC/ATSDR SVI).

Commercially available technology. A technology system that meets the requirements of either paragraph (1) or (2) of this definition.

(1) A domestic or foreign system that:

(i) Has both a proven and reliable operating history and proven performance data for at least 1 year specific to the use and operation of the proposed application;

(ii) Is based on established design and installation procedures and practices and is replicable;

(iii) Has professional service providers, trades, large construction equipment providers, and labor who are familiar with installation procedures and practices;

(iv) Has proprietary and balance of system equipment and spare parts that are readily available;

(v) Has service that is readily available to properly maintain and operate the system; and

(vi) Has an existing established warranty that is valid in the United States for major parts and labor.

(2) A domestic or foreign renewable energy system that has been certified by a recognized industry organization whose certification standards are acceptable to the Agency. A renewable energy system is considered to have demonstrated commercial availability if it has been certified by a recognized industry organization whose certification standards are acceptable to the Agency.

Examples of recognized industry organization whose certification standards are acceptable to the Agency include, but are not limited to:

(i) Small Wind Certification Council, *http://smallwindcertification.org/;*

(ii) Solar Rating and Certification Corporation, *http://www.solar-rating.org/;*

(iii) Florida Solar Energy Center, *http://www.fsec.ucf.edu/en/;*

(iv) American Wind Energy Association, *http://www.awea.org/;* and

(v) Intertek Small Wind Certification Program, *http://www.intertek.com/wind/small/directory/.*

Community. An organized group of individuals or business owners located in relatively the same area or having particular characteristics in common.

Community efficiency and weatherization. Community-based activities purposed to reduce energy costs for primarily low-income households by increasing the energy efficiency of their homes, while also ensuring their health and safety. Such activities include, but are not limited to, analysis and actions that would improve efficiency or weatherization based on that analysis, of all building systems —the building envelope, heating and cooling systems, electrical system, and electric baseload appliances.

Community energy plan. An economic development document focused on a region or municipality's energy costs, energy services, energy generation, consumption and service delivery. The community energy plan is a central component of the RECP action plan.

Community scale energy. A renewable energy project or purchasing program, within a defined geographic area, in which the benefits of the project flow to multiple customers such as individuals, businesses, nonprofits and other groups. To be a ''community-scale'' energy system, the generation must be managed by, or the generation project must at least be instigated by, a community that is engaged in some of the stages of: land-use planning, acquisition and installation of renewable equipment, maintenance and operation of this equipment, and the sale of energy, either electricity or heat, from it. With respect to size, community energy includes projects between the sizes of approximately fifty kilowatts to two megawatts which is substantially less generation than utility-scale installations, but more generation than would be used by the typical single end-user. Projects may be located on more than one site and have more than one user, *e.g.,* solar panels or small- to medium-sized wind turbines could be installed on separate properties and sent to a common transformer, or the equipment could be constructed within a common area, such as a public park.

Complete application. An application that contains all parts necessary for the Agency to determine applicant and project eligibility, score the application, and, where applicable, enable the Agency to determine the technical merit of the project.

Disadvantaged communities. Refers to the ''disadvantaged communities that have been historically marginalized and overburdened by pollution and underinvestment in housing, transportation, water and wastewater infrastructure, and health care,'' in Executive Order 14008, ''Executive

Order on Tackling the Climate Crisis at Home and Abroad,'' January 27, 2021.

Distressed energy communities. Twenty-five priority geographic areas hard-hit by declines in coal production and consumption and vulnerable to further economic distress with the closure of remaining coal mines and coal power plants. These areas are identified by the President's Interagency Working Group, established by Executive Order 14008, as prioritized for near-term investment using existing Federal agency programs and funding from the FY2021 Budget and the American Rescue Plan, as specified in the ''Initial Report to the President on Empowering Workers Through Revitalizing Energy Communities,'' Appendix B. Counties Within Priority Communities, Areas With High Concentrations Of Direct Coal Sector Jobs (*https://netl.doe.gov/sites/default/files/2021-04/Initial%20Report%20on%20Energy%20Communities_Apr2021.pdf*).

Distressed rural communities. Economically distressed communities located in rural areas.

Distributed renewable energy resources (DER). Small-scale units of power generation that operate locally and may be connected to a larger power grid at the distribution level, but may also operate independently or off the grid. Some examples of DER include but are not limited to: Solar photovoltaic panels, small wind, small biogas-fueled generators, electric vehicles and controllable loads, such as heating, ventilation and air conditioning (HVAC) systems and electric water heaters. An important distinction of a DER is that the energy it produces is often consumed close to the source. When using renewable power sources, the intermittent nature of some resources creates a need for using multiple renewable resources, as well as a means to tie them together, manage and store their output. Energy storage technologies such as batteries and fly wheels are generally necessary for hardware such as wind and other turbine types, solar panels, and tidal generation units. To get the most out of the energy produced, these power sources and storage devices need to be managed by way of electronic management devices, which include inverters and software such as Storage Distributed Resource Schedulers (SDRS).

DERs are commonly used to manage a number of smaller power generation and storage methods in residential, commercial and industrial sectors. They may be used by utility providers, businesses and individuals in the production and storage of renewable power or for backup power sources. These technologies are fundamental requirements of more advanced power grids such as smart grids and as such are considered eligible technologies for the purposes of the REPP.

District organization. An organization as defined in Section 300.3 of Title 13, Code of Federal Regulations (or a successor regulation).

Economically distressed communities. Communities identified by the Internal Revenue Service as Qualified Opportunity Zones; communities identified as disadvantaged or underserved communities by their respective States; communities identified on the Index of Deep Disadvantage referenced at *https://news.umich.edu/new-index-ranks-americas-100-most-disadvantaged communities/,* and communities that otherwise meet the definition of ''underserved communities'' as stated in this section.

Economic opportunity. A business situation or community circumstance which lends itself to the furtherance of the economic interests of the area and the local community by providing a catalyst or stimulus to growth or retention of commerce and industry in the area.

Energy burden. The percentage of gross household income spent on energy costs.

Environmental justice. The fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations and policies, and the equitable distribution of environmental benefits. Fair treatment means no group of people should bear a disproportionate share of the negative environmental consequences resulting from industrial, governmental, and commercial operations or policies. Meaningful involvement means people have an opportunity to participate in decisions about activities that may affect their environment or health.

Equity. 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 as established in Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (Jan. 20, 2021).

Indian Tribe. means the term as defined in 25 U.S.C. 5304(e).

Opportunity Zone Communities. Economically distressed communities, as defined by individual census tract, nominated by America's governors, and certified by the U.S. Secretary of the Treasury via a delegation of authority to the Internal Revenue Service. Under certain conditions, new investments in Opportunity Zones may be eligible for preferential tax treatment. There are 8,764 Opportunity Zone Communities in the United States.

Rural or rural area. An area of a State not in a city or town that has a population of more than 50,000 inhabitants, and which excludes certain populations pursuant to 7 U.S.C. 1991(a)(13)(H), according to the latest decennial census of the United States and not in the urbanized area contiguous and adjacent to a city or town that has a population of more than 50,000 inhabitants. In making this determination, the Agency will use the latest decennial census of the United States. The following exclusions apply:

(1) Any area in the urbanized area contiguous and adjacent to a city or town that has a population of more than 50,000 inhabitants that has been determined to be ''rural in character'' as follows:

(i) The determination that an area is ''rural in character'' will be made by the Under Secretary of Rural Development. The process to request a determination under this provision is outlined in paragraph (1)(ii) of this definition. The determination that an area is ''rural in character'' under this definition will apply to areas that are within:

(A) An urbanized area that has two points on its boundary that are at least 40 miles apart, which is not contiguous or adjacent to a city or town that has a population of greater than 150,000 inhabitants or the urbanized area of such a city or town; or

(B) An urbanized area contiguous and adjacent to a city or town of greater than 50,000 inhabitants that is within ¼ mile of a rural area.

(ii) Units of local government may petition the Under Secretary of Rural Development for a ''rural in character'' designation by submitting a petition to the appropriate Rural Development State Director for recommendation to the Administrator on behalf of the Under Secretary. The petition shall document how the area meets the

requirements of paragraph (1)(i)(A) or (B) of this definition and discuss why the petitioner believes the area is ''rural in character,'' including, but not limited to, the area's population density, demographics, and topography and how the local economy is tied to a rural economic base. Upon receiving a petition, the Under Secretary will consult with the applicable governor or leader in a similar position and request comments to be submitted within 5 business days, unless such comments were submitted with the petition. The Under Secretary will release to the public a Notice of a petition filed by a unit of local government not later than 30 days after receipt of the petition by way of publication in a local newspaper and posting on the Agency's website at *https://www.rd.usda.gov/onerdguarantee,* and the Under Secretary will make a determination not less than 15 days, but no more than 60 days, after the release of the Notice. Upon a negative determination, the Under Secretary will provide to the petitioner an opportunity to appeal a determination to the Under Secretary, and the petitioner will have 10 business days to appeal the determination and provide further information for consideration. The Under Secretary will make a determination of the appeal in not less than 15 days, but no more than 30 days.

(iii) Rural Development State Directors may also initiate a request to the Under Secretary to determine if an area is ''rural in character.'' A written recommendation should be sent to the Administrator, on behalf of the Under Secretary, that documents how the area meets the statutory requirements of paragraph (1)(i)(B) of this definition and discusses why the State Director believes the area is ''rural in character,'' including, but not limited to, the area's population density, demographics, topography, and how the local economy is tied to a rural economic base. Upon receipt of such a request, the Administrator will review the request for compliance with the ''rural in character'' provisions and make a recommendation to the Under Secretary. Provided a favorable determination is made, the Under Secretary will consult with the applicable Governor and request comments within 10 business days, unless gubernatorial comments were submitted with the request. A public Notice will be published by the State Office in accordance with paragraph (1)(ii) of this definition. There is no appeal process for requests made on the initiative of the State Director.

(2) An area that is attached to the urbanized area of a city or town with more than 50,000 inhabitants by a contiguous area of urbanized census blocks that is not more than two census blocks wide. Applicants from such an area should work with their Rural Development State Office to request a determination of whether their project is located in a rural area under this provision.

(3) For the Commonwealth of Puerto Rico, the island is considered Rural and eligible except for the San Juan Census Designated Place (CDP) and any other CDP with greater than 50,000 inhabitants. Areas within CDPs with greater than 50,000 inhabitants, other than the San Juan CDP, may be determined to be Rural if they are ''not urban in character.''

(4) For the State of Hawaii, all areas within the State are considered rural and eligible except for the Honolulu CDP within the County of Honolulu and any other CDP with greater than 50,000 inhabitants. Areas within CDPs with greater than 50,000 inhabitants, other than the Honolulu CDP, may be determined to be Rural if they are ''not urban in character.''

(5) For the purpose of defining a rural area in the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands, the Agency shall determine what constitutes rural and rural Area based on available population data.

Rural community. A community located in a rural area.

Rural energy community partnership (RECP). A partnership established to provide assistance to an identified community for purposes as specified in this Notice. Such purposes include but are not limited to: Community energy planning, capacity building, and technical assistance, community efficiency and weatherization and the deployment, installation, or equipping of community-scale renewable energy technologies or systems. The partnership must be comprised of at least two entities: A lead applicant entity (the Applicant) that satisfies section III. A(b) of this Notice, and one or more partner entities that satisfies section III. A(a) of this Notice. The applicant and partner entities as well as the partnership itself, are permitted to be pass-through entities and so must comply with 2 CFR 200.330 through 200.332. A partner entity may be considered a contracting entity hired to perform services. The partnership need not be located in the identified community but must demonstrate that it is actively engaged with members of the community and must provide assistance specifically to the identified community.

State. Any of the 50 States of the United States, the Commonwealth of Puerto Rico, the District of Columbia, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

Technical assistance. Managerial, financial and operational analysis and consultation by qualified independent providers to assist project owners in identifying and evaluating problems or potential problems and to provide training that enables project owners to successfully implement, manage, operate and maintain viable projects.

Underserved communities. Populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social and civic life, as exemplified by the list in the definition of ''equity.'' Communities (including urban or rural communities and Indian tribal communities) that have limited access to affordable, healthy foods, including fresh fruits and vegetables, in grocery stores or farmer-to-consumer direct markets and that have either a high rate of food insecurity or a high poverty rate as reflected in the most recent decennial census or another Agency-approved census. For purposes of this Notice, an underserved community also refers to a community with environmental justice concerns or vulnerable populations, including people of color, low income, rural, tribal, indigenous, and homeless populations that may be disproportionately impacted by environmental harms and risks and has a local environmental or public health issue that is identified in the applicant's required letter of intent or complete application.

Used equipment. Any equipment that has been used in any previous application and is provided in an ''as is'' condition.

II. Federal Award Information

Type of Award: Competitive Grant.

Available Funds: Under REPP, up to $10 million is made available until expended, to eligible participants. Of the total amount of available funds, not more than 20 percent or $2 million (or $400,000 on any individual award) is available for eligible project costs related to community energy planning, capacity building, technical assistance, community efficiency and weatherization. The balance of available funds but not less than 80 percent or $8 million is available for eligible project

costs related to the deployment, installation or equipping of community-scale renewable energy systems, technologies or resources.

Minimum Award: There is no minimum award.

Maximum Award: $2,000,000.

Anticipated Award Date: Spring 2022.

Approximate Number of Awards: The number of awards will depend on the number of eligible participants and the total amount of requested funds. Should every successful applicant be awarded the maximum amount available of $2 million, five awards will be made.

III. Eligibility Information

A. Eligible Applicants

Applicants must meet all the following eligibility requirements. Applications which fail to meet any of these requirements by the application deadline will be deemed ineligible and will not be considered.

(a) Eligible applicants to this program must be a RECP as defined in Section I.C. of this Notice, which may be comprised of, but are not limited to:

(1) Private entities;

(2) State and local entities;

(3) Indian Tribes;

(4) Municipalities and other public bodies.

(b) The RECP must have a lead applicant who is responsible for the administration of the grant proceeds and activities. A lead applicant must be one of the following entities:

(1) A District Organization;

(2) An Indian Tribe, or a political subdivision of an Indian Tribe, including a special purpose unit of an Indian Tribe, or a consortium of Indian Tribes;

(3) A State or a political subdivision of a State, including a special purpose unit of a State or local government engaged in economic development activities, or a consortium of political subdivisions; or

(4) A public or private nonprofit organization.

(c) Applicants must also meet the following requirements:

(1) Applicants must not have been debarred, suspended or otherwise excluded from, or ineligible for participation in, Federal assistance programs under Executive Order 12549, ''Debarment and Suspension.'' The Agency will check the Do Not Pay Portal (DNP) at the time of application and prior to funding any grant award to determine if the applicant has been debarred or suspended. In addition, an applicant will be considered ineligible for a grant due to an outstanding judgment obtained by the Government in a Federal Court (other than U.S. Tax Court), is delinquent on the payment of Federal income taxes, or is delinquent on Federal debt. The applicant must certify as part of the application that they do not have an outstanding judgment against them. The Agency will check the Do Not Pay System at the time of application and also prior to funding any grant award to verify this information.

(2) Any corporation must not have been convicted of a felony criminal violation under any Federal law within the past 24 months or have any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

B. Eligible Project

The purpose of the REPP is to provide financial assistance for rural communities to further develop renewable energy to help meet our nation's energy needs and combat climate change while prioritizing environmental justice, racial equity and economic opportunity.

To be eligible for this program, projects must contribute to the establishment or development of clean energy communities through the deployment of community-scale distributed renewable energy technologies or systems. Community scale means no larger than 2 megawatts in generation capacity, as defined in Section I. C. of this Notice. Eligible technologies are commercially available renewable energy systems *e.g.,* wind, solar, geothermal, hydroelectric, biomass or bioenergy, and distributed renewable energy resources as defined in Section I. C. of this Notice.

C. Priority Considerations

(a) Targeted assistance priority will be afforded to:

(1) Distressed Rural Communities;

(2) Distressed Energy Communities;

(3) Communities with High Energy Burdens (as identified by the Dept. of Energy, Low-Income Energy Affordability Data (LEAD) Tool);

(4) Centers for Disease Control—Socially Vulnerable Communities;

(5) Qualified Opportunity Zone Communities; and

(6) Disadvantaged Communities.

(b) Consideration for Alternative Renewable Energy Technologies—to communities that plan, execute, or deploy renewable energy generation technologies other than solar photovoltaic of at least 40 percent of total generation capacity as measured by megawatts of alternative generation capacity/megawatts of total generation capacity.

D. Cost Sharing or Matching

REPP requires matching funds of no less than 20 percent of the total eligible project costs of any activity carried out using REPP grant funds. Applicants will certify and demonstrate that any required matching funds will be available during the grant period and provide appropriate documentation with the application, as referenced in Section IV.B of this Notice. Matching funds are those project funds required to be provided by the applicant to receive a REPP grant. The applicant is responsible for securing the remainder of the total eligible project costs not covered by grant funds. Matching funds are comprised of eligible in-kind contributions from third parties or cash. In-kind contributions by the applicants cannot be used to meet the matching fund requirement.

Written commitments for matching funds (*e.g.,* letters of commitment and bank statements) must be submitted with the certification of matching funds when the application is submitted. Funds provided by the applicant in excess of the required matching funds are not matching funds. Passive third-party equity contributions are acceptable for REPP projects, including equity raised from the sale of Federal tax credits.

In the event of ineligible, overstated, or otherwise unsubstantiated claims in the certification of matching funds, the Agency reserves the right to adjust an application's grant request such that it is commensurate with eligible matching funds, or take otherwise action as deemed appropriate.

When calculating the matching funds requirement, round up or down to whole dollars as appropriate. To calculate the matching funds requirement, multiply the total eligible project costs of each eligible activity by 0.20. A list of requirements, inclusions, and exclusions pertaining to matching funds follows:

(1) Matching funds must meet all requirements (i)–(iv): The funds must be:

(i) Spent on eligible project costs during the grant period (see III. E.); Funds made available under REPP may be used for equipment, infrastructure,

and related expenses to support the deployment of community-scale distributed renewable energy technologies.

(ii) From eligible sources;

(iii) Spent in advance or as a pro-rata portion of grant funds being spent; and

(iv) Provided by the applicant in cash, or by third parties in the form of cash or in-kind contributions.

(2) Matching funds may include (i)–(iii):

(i) Other Federal grants as authorized;

(ii) Reasonable and customary travel expenses as long as written policies are established to explain how these costs are reimbursed, including the rates for reimbursement, which shall not exceed travel rates of the Federal government; and

(iii) The number of hours worked, provided the value associated with any in-kind contribution in the form of number of hours worked which is being used to meet a matching funds requirement is documented and verified.

(3) Matching funds cannot include (i)–(vi):

(i) Other Federal grants unless provided by authorizing legislation;

(ii) Cash or in-kind contributions donated outside of the grant period;

(iii) In-kind contributions provided by those individuals, businesses or cooperatives which are being potentially benefited by the assistance requested in the application; the Agency considers this to be a conflict of interest or the appearance of a conflict of interest;

(iv) In-kind contributions that the Agency determines are overvalued;

(v) Any project costs that are ineligible under the REPP; or

(vi) Any project costs that are restricted or unallowable under 2 CFR part 200.

Applicants may arrange with public or private entities such as, but not limited to, commercial technology providers, renewable energy promotional organizations, community development organizations, or Tribes, and other such entities, to secure such non-Federal funds or in-kind contributions.

As allowed by law, Federal assistance from other programs such as the Department of Energy Weatherization Assistance Program How to Apply for Weatherization Assistance | Department of Energy, State Energy Program State Energy Program | Department of Energy, Energy Transitions Initiative Partnership Project (ETIPP), as well as assistance from AmeriCorps Energy Corps Energy Corps—Helping Design a Green-Collar Workforce and the Environmental Protection Administration, Environmental Justice Grants, may be considered as Matching funds. There are also state-led programs and private sector efforts to help provide such funding, *e.g.,* the Database of State Incentives for Renewables & Efficiency, *https://www.dsireusa.org/.*

Funds from such programs may be included as part of any matching contribution requirement as long as the application demonstrates how the funds will contribute to REPP purposes and priorities and they are not ineligible as outlined above.

E. Eligible Project Costs

Eligible project costs are only those costs incurred during the grant period and that are directly related to the use and purposes of the REPP. Eligible project costs may include:

(1) Costs directly associated with activities to be carried out at or in direct partnership with the RECP including capacity building, community energy planning, technical assistance, and reporting results or outcomes to the Agency during the disbursement, performance, and annual reporting portions of this program, as well as materials, machinery and equipment associated with efficiency and weatherization, in an amount up to 20 percent of awarded funds;

(2) Retrofitting of existing, or purchase and installation of new, distributed renewable energy technologies, including any associated materials, machinery and equipment (limited to 2 megawatts; MW);

(3) Construction, retrofitting, and replacement;

(4) Fees for construction permits and licenses; and

(5) Professional service fees for qualified consultants, contractors, installers and other third-party service providers.

F. Ineligible Project Costs

The following are ineligible project costs for REPP:

(a) Used equipment;

(b) Vehicles;

(c) Business operations that derive more than 10 percent of annual gross revenue (including any lease income from space or machines) from gambling activity, excluding State or Tribal authorized lottery proceeds, conducted for the purpose of raising funds for the approved project as approved by the Agency;

(d) Business operations deriving income from activities of a sexual nature or illegal activities;

(e) Real property or land;

(f) Lease payments including lease to own and capitalized leases;

(g) Any project that creates or appears to be a conflict of interest. Conflict of interest, for purposes of this program includes, but is not limited to:

(i) Distribution or payment of grant and matching funds to an individual owner, partner, or stockholder, or to a beneficiary or immediate family of the applicant when the recipient will retain any portion of ownership in the applicant's or borrower's project. Grant and matching funds may not be used to support costs for services or goods going to, or coming from, a person or entity with a real or apparent conflict of interest.

(ii) Assistance to employees, relatives and associates. The Agency will process any requests for assistance under this subpart in accordance with 7 CFR part 1900, subpart D.

(iii) No member of or delegate to Congress shall receive any share or part of this grant or any benefit that may arise there from; but this provision shall not be construed to bar, as a contractor under the grant, a publicly held corporation whose ownership might include a member of Congress. The U.S. Department of Agriculture Departmental Regulations that contain other compliance requirements are referenced in paragraphs VI. and VIII., of this Notice. Applicants who are found to be or have been in violation of applicable Federal laws will be deemed ineligible;

(h) Funding of political or lobbying activities;

(i) Using funds to pay off any Federal direct or guaranteed loan or any other form of Federal debt;

(j) Any incurred expense, equipment purchase or paid service prior to the grant period; and

(k) Any expense associated with applying for this program except as described in E(1);

G. Other Eligibility Requirements

(a) Completeness. Applications that fail to meet all eligibility criteria by the application deadline or that fail to provide sufficient information to determine eligibility or priority scoring will not be considered for funding.

(b) Purpose eligibility. Applications must propose to establish clean energy communities through the deployment of community scale, distributed renewable energy technologies.

(c) Project eligibility. All project activities must be for the benefit of communities and their residents located in the rural service area.

(d) Environmental requirements. Applicants are cautioned against taking any actions or incurring any obligations prior to the Agency completing the environmental review that would either

limit the range of alternatives to be considered or that would have an adverse effect on the environment, such as the initiation of construction. If the applicant takes any such actions or incurs any such obligations, it could result in project ineligibility. Projects involving construction are subject to the environmental requirements of 7 CFR part 1970, local building codes and all Federal, State, Tribal, and local accessibility standards.

(e) Multiple application eligibility. Only one application can be submitted per applicant and the application must be submitted by the lead applicant as defined in section III. A. of this Notice. If two applications are submitted by the same lead applicant, both applications will be determined ineligible for funding. If it is determined that an applicant is affiliated with another entity that has also applied, both applications will be deemed ineligible and will not be considered. An affiliate is an entity controlling or having the power to control another entity, or a third party or parties that control or have the power to control both entities.

(f) Grant period. The grant period is not to exceed 36 months from date of award, unless otherwise specified in the financial assistance agreement or agreed to by the Agency. Under extenuating circumstances, a one-time, no cost extension for up to 24 months may be requested by the recipient.

(g) Satisfactory progress. The advancement of grant proceeds is contingent upon satisfactory progress. Satisfactory performance includes being up to date on all financial and performance reports as prescribed in the grant award, and current on tasks and timeframes for utilizing grant and matching funds as approved in the work plan and budget. Any changes in project cost, sources of funds, scope of services, or any other significant changes in the project or applicant, must be reported to and approved in writing by the Agency.

IV. Application and Submission Information

A. Electronic Application and Submission

Applications must be submitted in form and content as described in this section. Applications must be submitted electronically. No other form of application submission will be accepted. Applications will not be accepted through mail, courier delivery, in person delivery, email, or fax. Application guidance materials including a complete application guide and submission instructions are available on the Rural Energy Pilot Program website under the To Apply tab, *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program.*

B. Content and Form of Application Submission

(a) Applicants must submit required letters of intent and complete applications as noted in Section IV Application and Submission Information, by the dates identified in the **DATES** section of this Notice.

(b) Applications must contain all parts necessary for the Agency to determine applicant and project eligibility, conduct the technical evaluation, calculate a priority score, rank and compete the application, as applicable, in order to be considered. All applications determined to be insufficient for these purposes shall be deemed as incomplete and will not be considered for funding.

(c) Applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number which can be obtained at no cost via a toll-free request line at (866) 705–5711 or at *https://fedgov.dnb.com/webform.* Each lead applicant applying for grant funds (unless the applicant is an individual or Federal awarding agency that is excepted from the requirements under 2 CFR 25.110(b) or (c) or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to: (i) Register in the System for Award Management (SAM) before submitting its application; (ii) provide a valid unique entity identifier in its application; (iii) continue to maintain an active SAM registration with current information at all times while the Agency is considering an application or while a Federal grant award or loan is active; and, (iv) complete the Financial Assistance General Certifications and Representations in SAM. The Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

Applicants should be advised that a SAM registration may require up to 10 business days or more and are strongly cautioned against waiting until the application deadline date to begin.

(d) Please note that applicants can locate information on this funding opportunity at *http://www.grants.gov* by using the Assistance Listing Number (10.379) or the Funding Opportunity Number (RBCS–REPP–2021). The downloadable application package for this program will be available at *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program.*

(e) Letter of Intent

Applicants must submit a letter of intent (REPP LOI) prior to submitting a complete application. A Guide and instructions for submitting the REPP LOI are available on the Rural Energy Pilot Program website, under the To Apply tab, *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program.*

The REPP LOI may not exceed 15 standard (8.5″ x 11″) pages with 1″ borders on all sides, including any charts, tables, diagrams and illustrations. No information provided in excess of the 15-page limitation will be considered. The REPP LOI should be in a narrative form using a minimum of 11-point font and must consist of the following components:

(1) Rural Energy Community Partnership information including:

(i) The members and structure of the partnership;

(ii) the date of Charter or Articles of Incorporation;

(iii) the governance or leadership board;

(iv) identification of the lead applicant;

(v) description of each partner's ties to the region, their roles in the execution of the REPP pilot, and any history of previous collaboration among partners;

(vi) Description of the partnerships involvement with community leadership;

(vii) Statement on whether the partnership was formed specifically to apply for the REPP Grant or for other purposes, and;

(viii) the amount and source of anticipated matching funds to be provided.

(2) Description of whether the geographic region to be served is in a rural area as defined in Section I. C. of this Notice.

(3) Description of the geographic region to be served including county names and zip codes using the five indicators listed in (i). through (vi). below, and providing supporting documentation to describe the relative economic distress and energy burdened circumstances of the geographic region to be served:

(i) Using the *Distressed Communities Index* 2020 DCI Interactive Map—Economic Innovation Group (eig.org), to discuss relative distress scores and economic distress characteristics of the region such as unemployment rates and income levels.

(ii). Using the Low-Income Energy Affordability Data (LEAD) Tool | Department of Energy (*https://www.energy.gov/eere/slsc/maps/lead-tool*) to describe relative energy burden of geographic region to be served.

(iii). Using the CDC Social Vulnerability Index, *https://www.atsdr.cdc.gov/placeandhealth/svi/at-a-glance_svi.html* to describe the relative environmental health burden of the geographic region to be served.

(iv). Using the OZ Activity Map—Economic Innovation Group (eig.org) to document the geographic region to be served is a Qualified Opportunity Zone.

(v). Indicating whether/which county names/zip codes in the geographic region to be served are primarily of distressed communities with high concentrations of employment in coal, oil and gas industries, and coal-fired generation facilities transitioning away from fossil fueled energy production listed among the *Distressed Energy Communities* identified here, *https://ruraldevelopment.maps.arcgis.com/apps/webappviewer/index.html?id=86027863e066487ca1b33dc9217a70d1*.

(vi). Disadvantaged communities—Provide a brief narrative with supporting information to demonstrate how the geographic region to be served meets the definition of a Disadvantaged Community.

(4) Description of how REPP resources for community energy planning, human capacity building, technical assistance, efficiency and weatherization will be used by the RECP to address the relative economic distress and energy burdened circumstances of the geographic region to be served.

(5) Identification of, to the extent possible, all distributed renewable energy technologies and activities that will be prioritized and executed by the RECP to address the relative economic distress and energy burdened circumstances of the geographic region to be served.

(i) Discussion of any specific plans, activities or priorities for solar photovoltaic renewable energy technology to be deployed.

(ii) Discussion of any specific plans, activities or priorities for renewable energy technologies other than solar photovoltaic, such as wind, geothermal, biomass, bioenergy, micro hydroelectric, to be deployed.

(iii) Discussion of any specific plans, activities or priorities for distributed energy storage or management technologies, *e.g.,* batteries, flywheels, smart grids, etc., as defined in Section I. C. of this Notice.

(iv) Information on any electric utilities, firms or industries involved as well as any existing interconnections and networks (or lack thereof) in the geographic region to be served.

(v) Description of any participation and scale of small and disadvantaged businesses that may be involved. Describe the opportunities or potential for economic growth in the region and any competitive advantages that may exist by virtue of the RECP.

(vii) An executive summary, project action plan and scope of work, including if the proposal is a portion of a larger project (if so provide brief summary of larger project). Include the RECP's strategy, activities, budget, goals and objectives for the use of REPP funds. These objectives may include but are not limited to the ability to withstand disruptive events, economic and energy resilience, increased environmental justice, improved racial equity, expanded economic opportunity, and the stability or diversification of distributive energy resources.

Include proposed performance measures that express successes and challenges of meeting the RECP's goals and objectives and report its accomplishments during the grant period and provide annual outcome reports for three years after project completion. Performance measures may include but are not limited to renewable energy generation and energy efficiency/energy savings (measured in kilowatt hours), project sustainability and resilience measured by inclusion of institutional partners and continued commitment of project financing, and community benefits measured in terms of power purchase agreement/subscription income (in dollars per kilowatt hour), reduced greenhouse gas/carbon dioxide emissions (in metric tons of CO_2 equivalence), reduced energy burdens (in percentage of household incomes), measured environmental justice, measured equity, measured economic opportunity, etc.

The applicant should also provide information on the sustainability of the RECP at the conclusion of the REPP grant period.

(6) The REPP LOI must be signed by a senior executive from the lead applicant entity who shall be responsible for the administration of the grant proceeds and activities.

(f) Complete Application

A complete application must contain all the required forms and proposal elements as described in this section. To be eligible to submit a complete application, applicants must first have submitted to the Agency a required LOI as specified in Section IV. B. (1) of this Notice. Applicants that have submitted a required LOI and have received a letter of invitation from the Agency may submit a Complete Application. A Guide and instructions for submitting the Complete Application are available on the Rural Energy Pilot Program website, under the To Apply tab, *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program.*

Applications lacking sufficient information for the Agency to determine eligibility and score the application will be deemed as incomplete and will not be considered for funding. Information submitted after the application deadline will not be accepted.

The lead applicant must be registered in the System for Award Management (SAM) and submit a complete application consisting of the elements specified in Section IV. B. (2) (a)(l) as applicable to this section.

The Agency requires the following information as part of the application:

(1) Form SF–424, ''Application for Federal Assistance.'' In 8.a. please place DUNS (or replacement identifier number (in parentheses)) after legal name;

(2) Form SF–424C, ''Budget Information- Construction Programs,'';

(3) Form SF–424D, ''Assurances—Construction Programs,'';

(4) SF–LLL, ''Disclosure of Lobbying Activities'';

(5) RD Form 400–1, ''Equal Opportunity Agreement,'';

(6) RD Form 400–4, ''Assurance Agreement'';

(7) Environmental checklist;

(8) Certification of matching funds;

(9) Certification that the lead applicant is a legal entity in good standing (as applicable) and operating in accordance with the laws of the state(s) or Tribe(s) where the applicant exists;

(10) The application must identify whether or not the lead applicant has a known relationship or association with an Agency employee. If there is a known relationship, the lead applicant must identify each Agency employee with whom the lead applicant has a known relationship; and

(11) Revisions and updates to materials submitted to the Agency with the LOI as specified in Section IV. B. (1) of this Notice.

(12) Narrative descriptions and supporting materials including proposed performance measures, as appropriate, addressing each of the priority scoring criteria in accordance with Sections V. Application Review Information, paragraphs A, and B of this Notice regarding the RECP's ability and commitment to develop of community-scale renewable energy technologies or systems; proposed community and regional objectives and impacts; geographic region to be served of significant consequence to the REPP priorities of advancing environmental justice, racial equity, and economic opportunity; strength of local support of the RECP, activities, projects, and entrepreneurial commitment; RECP's readiness to administer the REPP grant successfully; and key Administration priorities.

(13) Any other information deemed necessary and requested by the Agency due to the facts and circumstances for a particular application.

C. Submission Date and Time

(a) Letters of intent must be submitted in the manner specified for letters of intent in the **DATES** section of this Notice, to be eligible for grant funding.

(b) Complete applications must be submitted in the manner specified for complete applications in the **DATES** section of this Notice, to be eligible for grant funding.

(c) Applicants are advised to review the REPP website for instructions on registering your organization as soon as possible to ensure that you can meet the electronic application deadline. Applications will not be accepted after the deadline.

D. Intergovernmental Review of Applications

Executive Order (E.O.) 12372, ''Intergovernmental Review of Federal Programs,'' does not apply to this program.

E. Funding Restrictions

Funding limitations as specified in (a) thru (f), apply to applications submitted under this Notice.

(a) Only one REPP application may be submitted per REPP applicant. A REPP applicant may receive only one award in this competition. If it is determined that an applicant is affiliated with another entity that has also applied, both applications will be deemed ineligible and will not be considered.

(b) There is no minimum REPP grant award.

(c) The maximum REPP grant award is not to exceed $2,000,000.

(d) REPP grants are awarded on a cost share basis for not more than 80 percent of total eligible project costs.

(e) No REPP grant award may exceed an amount calculated as 80 percent of total eligible project costs or the maximum REPP grant award amount of $2,000,000, whichever is the lesser. Not more than 20 percent of awarded funds, or $400,000, whichever is the lesser, may be used for eligible project costs directly associated with activities to be carried out at or in direct partnership with the RECP including capacity building, community energy plans, technical assistance, and reporting results or outcomes to the Agency during the disbursement, performance, and annual reporting portions of this program, as defined in Section I.C. of this Notice, as well as materials, machinery and equipment associated with efficiency and weatherization. Administrative (indirect) costs of the grantee will not exceed 10% of the grant amount for the duration of the project. Said administrative costs limitation is to be included in the 20 percent limitation specified in this subsection.

(f) Project funds, including grant and matching funds, cannot be used for ineligible grant purposes as provided in Section IV. B. of this Notice, 2 CFR part 200, subpart E, ''Cost Principles,'' and the most current Federal Acquisition Regulation or successor regulations.

F. Compliance With Other Federal Statues and Other Submission Requirements

(a) Environmental information. National Environmental Policy Act. All recipients under this Notice are subject to the requirements of 7 CFR part 1970. However, technical assistance awards under this Notice are classified as a Categorical Exclusion according to 7 CFR 1970.53(b), and usually do not require any additional documentation. The Agency will review each grant application to determine its compliance with 7 CFR part 1970. The applicant may be asked to provide additional information or documentation to assist the Agency with this determination. Applicants are advised in all cases of new facilities construction to contact the RD State Environmental Coordinator to determine environmental requirements as soon as practicable.

(b) Civil Rights compliance requirements. All grants made under this Notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973.

V. Application Review Information

The Agency's National Office will review applications to determine if they are eligible for assistance based on the requirements specified in this Notice, and other applicable Federal regulations.

A priority score will be afforded to complete applications deemed eligible to compete by an evaluation panel of subject matter experts from USDA/DOE/EPA (and others as required by the Agency), in accordance with the point allocation specified in this Notice. Given the purpose of the REPP, higher priority will be afforded to RECP projects deemed most likely to develop renewable energy to help meet our nation's energy needs and combat climate change while prioritizing environmental justice, racial equity, and economic opportunity.

Applications will be selected for funding by ranked order until the funding limitation of $10 million has been reached. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion.

A. Scoring Criteria

The Agency will score each complete and eligible REPP application using the criteria specified in paragraphs (a) through (e) of this section with a maximum score of 100 points possible.

Applications will be evaluated based on the following: Impact to the community, support from relevant decision makers and community leaders, likelihood that projects can be completed, and alignment with REPP goals. Points will be allowed only for factors indicated by well-documented plans which, in the opinion of the Agency, provide assurance that the projects have a high probability of being accomplished. Points will be awarded at the discretion of the Agency to each scoring criteria with a minimum and maximum number of points available. Applicants that demonstrate the experience or ability to deliver the stated criteria will be awarded higher points in that criteria.

(a) Further develop renewable energy. Application materials demonstrate the RECP's ability and commitment to addressing Priority Considerations as specified in Section III. C., of this Notice. One point will be awarded for each of the six priority considerations being proposed to be served by the project as outlined in Section III.C.(a). Up to six points will be awarded for projects that plan, execute, or deploy renewable energy generation technologies other than solar photovoltaic of at least 40 percent of

total generation capacity as measure by megawatts of alternative generation capacity/megawatts of total generation capacity. Up to six points will be awarded for projects that can be delivered within 36 months of the grant award. Up to seven points will be awarded to projects leveraging other Federal, State, Tribal, and local assistance resources for community planning, human-capacity building, technical assistance, efficiency, weatherization, and improvements in high-speed broadband service to the region.

Points are awarded on a scale of 0 to 25 with a maximum of 25 points being awarded. (b) Community and regional impacts. Application materials describe in full, the community objectives to be achieved through RECP efforts at the completion of REPP assistance. These objectives are to be identified by the community and can include the ability to withstand disruptive events, economic and energy resilience, increased environmental justice, improved racial equity, expanded economic opportunity, and the stability or diversification of distributive energy resources.

Points are awarded on a scale of 0 to 25 with a maximum of 25 points being awarded.

(c) Targeted region. Application materials should describe the geographic region to be served, including county names and zip codes, and demonstrate that the geographic region served by the RECP is of significant consequence to the REPP priorities of advancing environmental justice, racial equity, and economic opportunity.

(1) Using the *Distressed Communities Index* 2020 DCI Interactive Map—Economic Innovation Group (eig.org), discuss relative distress scores and economic distress characteristics of the region such as unemployment rates and income levels. A maximum of 5 points may be awarded under this sub-criteria.

(2) Using Low-Income Energy Affordability Data (LEAD) Tool | Department of Energy describe relative energy burden of geographic region to be served. A maximum of 5 points may be awarded under this sub-criteria.

(3) Using CDC Social Vulnerability Index, *https://www.atsdr.cdc.gov/placeandhealth/svi/at-a-glance_svi.html* describe the relative environmental health burden of the geographic region to be served. A maximum of 5 points may be awarded under this sub-criteria.

(4) Using the OZ Activity Map—Economic Innovation Group (eig.org) document the geographic region to be served as a Qualified Opportunity Zone. A maximum of 5 points may be awarded under this sub-criteria.

(5) Indicate which counties or zip codes in the geographic region to be served are primarily distressed communities with high concentrations of employment in coal, oil and gas industries, and coal-fired generation facilities transitioning away from fossil fueled energy production listed among the *Distressed Energy Communities* identified at: *https://ruraldevelopment.maps.arcgis.com/apps/webappviewer/index.html?id=86027863e066487ca1b33dc9217a70d1.* A maximum of 5 points may be awarded under this sub-criteria.

(6) Disadvantaged communities—Provide a brief narrative with supporting information to demonstrate how the geographic region meets the definition of a Disadvantaged Community. A maximum of 5 points may be awarded under this sub-criteria.

Points are awarded on a scale of 0 to 25 with a maximum of 25 points being awarded.

(d) Project and community support. Applications should demonstrate the strength of local support of the RECP, activities, projects, and entrepreneurial commitment. Points will be awarded for the RECP's demonstration of its sources of funding, personnel and technical resources committed to the project; inclusion of institutional partners expanding access to capital and willingness to potentially invest in projects emerging from the RECP. A maximum of 10 points may be awarded under this sub-criteria. Points shall also be awarded for demonstrated resources that will sustain the project beyond the term of the REPP grant period. A maximum of 5 points may be awarded under this sub-criteria.

Points are awarded on a scale of 0 to 15 with a maximum of 15 points being awarded.

(e) Demonstrated readiness and likelihood of success. Application materials demonstrate the RECP's readiness to administer the REPP grant successfully, with strong documentation to indicate the likelihood of implementing technical assistance, weatherization, energy efficiency and renewable energy projects in the community (a maximum of 3 points may be awarded under this sub-criteria); a stakeholder engagement plan (a maximum of 2 points may be awarded under this sub-criteria); the existence of an energy resilience goal (a maximum of 3 points may be awarded under this sub-criteria); and the availability or expectation of project financing (a maximum of 2 points may be awarded under this sub-criteria).

Points are awarded on a scale of 0 to 10 with a maximum of 10 points being awarded.

B. Administrator Points

The Agency retains the discretion to afford priority to applications that will advance key Administration priorities:

(1) Assist Rural communities recover economically from the impacts of the COVID–19 pandemic, particularly disadvantaged communities;

(2) Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects; and

(3) Reduce climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

The Agency also retains the discretion to afford priority to applications that achieve geographic distribution of REPP grant awards across the maximum number of States and target diverse communities.

A maximum of up to 10 points will be awarded, with justification, at the discretion of the Administrator.

C. Review and Selection Process

The Agency's National Office will review applications to determine if they are complete and eligible for assistance based on requirements specified in this Notice, and other applicable Federal regulations. Applications so deemed, will be evaluated by an independent review panel and afforded a priority score in accordance with the point allocation as specified in Section V. A. of this Notice.

The Administrator may choose to award up to 10 Administrator priority points based on the criterion specified in Section V. B. of this Notice. Any awarded Administrator points will be added to the cumulative score for a total possible score of 110 points.

Applications will be selected for funding according to rank, beginning with the highest priority score and proceeding until the available funding is exhausted. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion; as in the event of a ranked tie among two or more applications. Unfunded applications will not be carried forward into any future competition. Successful applicants must comply with requirements identified in Section VI. Federal Award Administration Information.

VI. Federal Award Administration Information

A. Federal Award Notices

Applicants selected for funding, will receive a signed Notice of Federal award

by postal or electronic mail containing instructions and requirements necessary to proceed with execution and performance of the award.

Applicants selected for funding must comply with all applicable statutes, regulations, and Notice requirements before the grant award will be funded.

Applicants not selected for funding will be notified in writing and informed of any review and appeal rights. Awards to successfully appealed applications will be limited to available funding.

B. Administrative and National Policy Requirements

Additional requirements that apply to grantees selected for this program can be found in the Grants and Agreements regulations codified in 2 CFR parts 180, 400, 415, 417, 418, 421; 2 CFR parts 25 and 170; and 48 CFR 31.2, and successor regulations to these parts.

In addition, all recipients of Federal financial assistance are required to report information about first tier subawards and executive compensation (see 2 CFR part 170). Grantees are required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) reporting requirements (see 2 CFR 170.200(b), unless exempt under 2 CFR 170.110(b)).

The following additional requirements apply to grantees selected for awards within this program: (a) Execution of an Agency-approved financial assistance agreement; and (b) acceptance of a written letter of conditions; and submission of the following Agency forms: (1) Form RD 1940–1, ''Request for Obligation of Funds.'' (2) Form RD 1942–46, ''Letter of Intent to Meet Conditions.'' and (3) Form RD 400–1 for construction projects.

C. Reporting

Financial and project performance reports must be provided by grantees and contain the information specified in paragraphs (1) and (2) of this section.

(1) Semi-Annual Reports. After grant approval and through grant completion, grantees are required to provide an SF–425, ''Federal Financial Report,'' and a performance report on a semiannual basis (due 30 working days after the end of the semiannual period). For the purposes of this grant, semiannual periods end on June 30th and December 31st.

The project performance reports shall include the following:

(a) A listing and description of all activities funded with grant proceeds and matching funds;

(b) A description or assessment of progress towards program initiatives identified in the application for the grant and a discussion of any issues or challenges which may have occurred and the steps taken to mitigate or address them; and

(c) A measurement of progress during the project period that incorporates, but is not limited to, the following performance goals as agreed to by the Agency and as specified in the letter of conditions—renewable energy generation from solar PV & alternative renewable energy systems (in thousands of kilowatt hours); energy savings from efficiency & weatherization (in hundreds of kilowatt hours); project sustainability & resilience; and community benefits such as but not limited to power purchase agreement/subscription income (in dollars per kilowatt hour), reduced greenhouse gas/carbon dioxide emissions (in metric tons of CO_2 equivalence), reduced energy burdens (in percentage of household incomes), measured environmental justice, measured equity, and measured economic opportunity.

(2) Annual Outcome Reports. Upon project completion, grantees are required to provide an annual outcome report for three years. The first report is due at the completion of the first full calendar year following the year in which the project was completed. The remaining reports are required for subsequent calendar years. Reports are due January 31st. The annual outcome report shall continue to incorporate the performance goals as identified in VI. C. 1 (c) above (reported on an annual basis), as well as any other measures specified in the financial assistance agreement and letter of conditions.

VII. Agency Contacts

For further information contact: Anthony Crooks: telephone (202)205–9322, email: *RuralEnergyPilotProgram@usda.gov* or consult the REPP program web page at *https://www.rd.usda.gov/programs-services/energy-programs/rural-energy-pilot-program* where program guidance as well as application and matching funds templates may be obtained.

VIII. Other Information

A. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), RBCS requested that the Office of Management and Budget (OMB) conduct an emergency review by January 19, 2022 of a new information collection that contains the Information Collection and Recordkeeping requirements contained in this notice. In addition to the emergency clearance, the regular clearance process is hereby being initiated to provide the public with the opportunity to comment under a full comment period, as the Agency intends to request regular approval from OMB for this information collection. Comments from the public on new, proposed, revised, and continuing collections of information help the Agency assess the impact of its information collection requirements and minimize the public's reporting burden.

Comments may be submitted regarding this information collection by the following method:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov,* and, in the lower ''Search Regulations and Federal Actions'' box, select ''RBCS'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select Docket No. RBS–21–Business-0030 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.

The burden for the REPP collection of information includes both the upfront one-time application and the on-going reporting, which will include mid-year and an annual reporting. The reporting may include additional reports for projects that run longer. Comments are invited on (a) the accuracy of the agency's estimate of burden including the validity of the methodology and assumption used; (b) ways to enhance the quality, utility, and clarity of the information to be collected; and (c) ways to minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques on other forms and information technology.

Title: Rural Energy Pilot Program (REPP).

OMB Control Number: 0570–New.

Type of Request: New Information Collection.

Abstract: The purpose of the REPP to further develop renewable energy to help meet our nation's energy needs and combat climate change while prioritizing environmental justice, racial equity, and economic opportunity.

Cost-share grants of up to 80 percent of total eligible project costs but not more than $2 million will be made available to assist eligible entities with

developing, installing, equipping, and maintaining community scale distributive energy resources

The information solicited from applications by this NOFO is required to (1) determine whether participants meet the eligibility requirements to be a recipient of grant funds; (2) evaluate project eligibility; (3) determine technical and financial viability; (4) calculate priority scores and rank in order to compete the applications for funding. Lack of adequate information for these purposes could result in the improper administration and appropriation of Federal grant funds.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 11 hours per response.

Estimated Number of Respondents: 25.

Estimated Total Annual Responses: 325.

Estimated Total Recordkeeping Hours: 15.

Estimated Total Burden Hours: 3,462.

Estimated Total Annual Burden (including recordkeeping) on Respondents: 3,477 hours.

Copies of this information collection can be obtained from MaryPat Daskal, Regulatory Division Team 2, Rural Development Innovation Center, U.S. Department of Agriculture, 1400 Independence Ave. SW, Washington, DC 20250. Phone: 202–690–4492. All responses to this information collection and recordkeeping Notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

B. Nondiscrimination Statement

In accordance with Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, 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.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *https://www.ocio.usda.gov/document/ad-3027,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Karama Neal,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2022–00943 Filed 1–18–22; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Information Systems Technical Advisory Committee; Notice of Partially Closed Meeting

The Information Systems Technical Advisory Committee (ISTAC) will meet on February 2, 2022, at 1:00 p.m., Eastern Standard Time. The meetings will be available via teleconference. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to information systems equipment and technology.

Wednesday, February 2

Open Session

1. Welcome and Announcements
2. Working Group Reports
3. Industry Presentation

Closed Session

4. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than January 26, 2022.

To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that public presentation materials or comments be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 7, 2022, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. (l0)(d))), that the portion of the meeting concerning trade secrets and commercial or financial information deemed privileged or confidential as described in 5 U.S.C. 552b(c)(4) and the portion of the meeting concerning matters the disclosure of which would be likely to frustrate significantly implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 10(a)(1) and l0(a)(3). The remaining portions of the meeting will be open to the public.

For more information, contact Yvette Springer via email.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2022–00885 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that

countervailable subsidies are being provided to producers and exporters of certain corrosion-resistant steel products from the Republic of Korea. The period of review (POR) is January 1, 2019, through December 31, 2019. Commerce is also rescinding the review with respect to Dongkuk Steel Mill Co., Ltd. (Dongkuk).

DATES: Applicable January 19, 2022.

FOR FURTHER INFORMATION CONTACT: Joshua Simondis or Dennis McClure, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0608 or (202) 482–5973, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this review on July 16, 2021.[1] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[2]

Scope of the Order

The products covered by this order are certain corrosion-resistant steel products. For a complete description of the scope of this order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in interested parties' case briefs are addressed in the Issues and Decision Memorandum accompanying this notice. A list of the issued raised by parties, and to which Commerce responded in the Issues and Decision Memorandum, is provided in Appendix I to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties, and for the reasons explained in the Issues and Decision Memorandum, we made changes to the *Preliminary Results.*

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[3] For a description of the methodology underlying all of Commerce's conclusions, *see* the Issues and Decision Memorandum.

Rescission of Administrative Review, in Part

As noted in the Issues and Decision Memorandum, Commerce inadvertently included Dongkuk as a respondent company in this administrative review. Accordingly, we are rescinding the review with respect to Dongkuk. For further discussion, *see* ''Rescission of Administrative Review, in Part'' section in the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

There are 35 companies for which a review was requested, but which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. For these 35 companies, we applied the subsidy rate calculated for KG Dongbu Steel Co., Ltd. (KG Dongbu Steel) (formerly Dongbu Steel Co., Ltd.) and its cross-owned affiliate, Dongbu Incheon Steel Co., Ltd., as the only rate calculated for a mandatory respondent that was above *de minimis* and not based entirely on facts available. This methodology for establishing the subsidy rate for the non-selected companies is consistent with our practice and with section 705(c)(5)(A) of the Act.

Final Results of Administrative Review

We determine that, for the period January 1, 2019, through December 31, 2019, the following total estimated net countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
KG Dongbu Steel Co., Ltd. (formerly Dongbu Steel Co., Ltd.)[4]/ Dongbu Incheon Steel Co., Ltd	10.51
Hyundai Steel Company	*0.47
Non-Selected Companies Under Review[5]	10.51

*(*de minimis*).

Assessment Rate

Pursuant to 19 CFR 351.212(b)(2), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed companies at the applicable *ad valorem* assessment rates listed. 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 Rates

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposits, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

[1] *See Certain Corrosion-Resistant Steel Products from the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review; 2019,* 86 FR 37740 (July 16, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results and Partial Rescission of the 2019 Administrative Review of the Countervailing Duty Order on Certain Corrosion-Resistant Steel Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[4] Dongbu Steel Co., Ltd. changed its name to KG Dongbu Steel Co., Ltd. in 2020.

[5] *See* Appendix II.

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: January 12, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

Appendix II

List of Non-Selected Companies

1. Ajin H & S Co., Ltd.
2. AJU Steel Co., Ltd.
3. B&N International
4. CDS Global Logistics
5. Dong A Hwa Sung Co., Ltd.
6. Dongkuk International, Inc.
7. Korea Clad Tech. Co., Ltd.
8. Pantos Logistics Co., Ltd.
9. PL Special Steel Co., Ltd.
10. POSCO
11. POSCO C&C
12. POSCO Coated & Color Steel Co., Ltd.
13. POSCO Daewoo Corp.
14. Samsung C&T Corporation
15. Samsung Electronics Co., Ltd.
16. Sanglim Steel Co., Ltd.
17. SeAH Coated Metal
18. SeAH Steel Corporation
19. Seajin St. Industry, Ltd.
20. Sejung Shipping Co., Ltd.
21. Seun Steel Co., Ltd.
22. Segye Chemical Industry Co., Ltd.
23. Shandongsheng Cao Xian Yalu Mftd.
24. Shengzhou Hanshine Import and Export Trade
25. Soon Hong Trading Co., Ltd.
26. Southern Steel Sheet Co., Ltd.
27. SSangyong Manufacturing
28. Sung A Steel Co., Ltd.
29. SW Co., Ltd.
30. SY Co., Ltd.
31. Syon
32. TCC Steel. Co., Ltd.
33. Young Steel Korea Co., Ltd.
34. Young Sun Steel Co.
35. Young Steel Co.

[FR Doc. 2022–00939 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–884]

Glycine From India: Final Results of Countervailing Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of glycine from India during the period of review (POR), September 4, 2018, through December 31, 2019.

DATES: Applicable January 19, 2022.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0698.

SUPPLEMENTARY INFORMATION:

Background

On July 16, 2021, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register**.[1] On October 21, 2021, Commerce extended the final results of review by 60 days, until January 12, 2022.[2] On November 16, 2021, Commerce issued a post-preliminary decision.[3] We invited parties to comment on the *Preliminary Results* and on the Post-Preliminary Decision. On November 29 and 30, 2021, case briefs were timely filed by GEO Specialty Chemicals, Inc. (the petitioner), Avid Organics Private Limited (Avid), and Kumar Industries, India (Kumar).[4] On December 6, 2021, timely rebuttal briefs were submitted to Commerce by the petitioner, Avid, Kumar and Paras Intermediates Private Limited (Paras).[5] For a full description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[6]

Scope of the Order

The merchandise covered by the order is glycine from India. For the complete description of the scope of the order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in interested parties' briefs are addressed in the Issues and Decision Memorandum. A list of the issues raised by interested parties, and

[1] *See Glycine from India: Preliminary Results of the Countervailing Duty Administrative Review; 2018–2019,* 86 FR 37738 (July 16, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Glycine from India: Extension of Time Limit for Final Results of Countervailing Duty Administrative Review,'' dated October 21, 2021.

[3] *See* Memorandum, ''Countervailing Duty Administrative Review of Glycine from India, 2018–2019: Post-Preliminary Decision,'' dated November 16, 2021 (Post-Preliminary Decision).

[4] *See* Petitioner's Letter, ''Glycine from India: GEO Specialty Chemical's Case Brief,'' dated November 29, 2021; Avid's Letter, ''Glycine from India: Case Brief—Avid Organic's Pvt. Ltd.,'' dated November 29, 2021; and Kumar's Letter, ''Certain Glycine from India (C–533–884) Kumar Industries—Case Brief,'' dated November 30, 2021.

[5] *See* Petitioner's Letter, ''Glycine from India: GEO Specialty Chemicals' Rebuttal Brief,'' dated December 6, 2021; Avid's Letter, ''Glycine from India: Rebuttal Brief—Avid Organics Pvt. Ltd.,'' dated December 6, 2021; Kumar's Letter, ''Certain Glycine from India (C–533–884) Kumar Industries—Rebuttal Brief,'' dated December 6, 2021; and Paras' Letter, ''Paras Intermediates Private Limited (''Paras'') Administrative Rebuttal Brief: Countervailing Duty Investigation on Glycine from India,'' dated December 6, 2021.

[6] *See* Memorandum, ''Glycine from India: Issues and Decision Memorandum for the Final Results of Countervailing Duty Administrative Review; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

to which Commerce responded in the Issues and Decision Memorandum, is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.*

Changes Since the Preliminary Results

Based on our review and analysis of the comments received from parties, we made certain changes to the net subsidy rates calculated for Avid and Kumar, and for companies not selected for individual review. These changes are explained in the Issues and Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and the subsidy is specific.[7] For a full description of the methodology underlying all of Commerce's conclusions, *see* the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

For the companies not selected for individual examination, because the rates calculated for Avid and Kumar are above *de minimis* and not based entirely on facts available, we applied a subsidy rate based on a weighted-average of the subsidy rates calculated for Avid and Kumar using publicly ranged sales data submitted by the respondents.[8] This is consistent with the methodology that we would use in an investigation to establish the all-others rate, pursuant to section 705(c)(5)(A) of the Act.

Final Results of Administrative Review

We determine the following net countervailable subsidy rates for the period September 4, 2018, through December 31, 2019:

Company	2018 Subsidy rate (percent *ad valorem*)	2019 Subsidy Rate (percent *ad valorem*)
Avid Organics Private Limited	5.01	5.16
Kumar Industries (India)	11.81	3.75
Mulji Mehta Enterprises	3.92	4.35
Mulji Mehta Pharma	3.92	4.35
Paras Intermediates Private Limited	3.92	4.35
Rudraa International	3.92	4.35
Studio Disrupt	3.92	4.35

Disclosure

Commerce will disclose to the parties in this proceeding the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to 19 CFR 351.212(b)(2), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed companies at the applicable *ad valorem* assessment rates listed. 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**.[9] 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 to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the 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, Commerce will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of these final results, shall remain in effect until further notice.

Administrative Protective Order

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the 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 return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 12, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See* Memorandum, ''Final Results Calculation of Subsidy Rate for Non-Examined Companies Under Review,'' dated concurrently with this notice.

[9] *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).

[FR Doc. 2022–00954 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–874]

Certain Steel Nails From the Republic of Korea: 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) determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), July 1, 2019, through June 30, 2020.

DATES: Applicable January 19, 2022.

FOR FURTHER INFORMATION CONTACT: Eva Kim, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8283.

SUPPLEMENTARY INFORMATION:

Background

On July 19, 2021, Commerce published the preliminary results of the 2019–2020 administrative review of the antidumping duty (AD) order on certain steel nails from the Republic of Korea (Korea).[1] We invited interested parties to comment on the *Preliminary Results.* A full description of the events since the *Preliminary Results* is contained in the Issues and Decision Memorandum.[2] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The products covered by the AD *Order* are steel nails from Korea. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in the appendix to this notice and addressed in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our analysis of the comments received, we have made no changes to the margin calculation for the sole mandatory respondent, Daejin Steel Company (Daejin), since the *Preliminary Results.*

Rate for Non-Examined Company

Generally, when calculating margins for non-selected respondents, Commerce looks to section 735(c)(5) of the Act for guidance, which provides instructions for calculating the all-others margin in an investigation. Section 735(c)(5)(A) of the Act provides that when calculating the all-others margin, Commerce will exclude any zero and *de minimis* weighted average dumping margins, as well as any weighted-average dumping margins based on total facts available. Accordingly, Commerce's usual practice has been to average the margins for selected respondents, excluding margins that are zero, *de minimis,* or based entirely on facts available. In this review, we calculated a weighted-average dumping margin of 3.22 percent for Daejin, the sole mandatory respondent. In accordance with section 735(c)(5)(A) of the Act, Commerce assigned Daejin's calculated weighted-average dumping margin, *i.e.,* 3.22 percent, to the non-selected company in these final results. Accordingly, we have applied a rate of 3.22 percent to the non-selected company, *i.e.,* Koram Inc.

Final Results of Administrative Review

Commerce determines that the following weighted-average dumping margins exist for the period July 1, 2019, through June 30, 2020:

Producer/exporter	Weighted-average dumping margin (percent)
Daejin Steel Company	3.22
Koram Inc	3.22

Disclosure

Commerce intends to disclose the calculations performed for these final results within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) the Act and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. We intend to calculate importer- (or customer-) specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for each importer (or customer's) examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1). Where an importer- (or customer-) specific rate is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such

[1] *See Certain Steel Nails from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 38015 (July 19, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Certain Steel Nails from the Republic of Korea; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 80 FR 39994 (July 13, 2015) (*Order*).

instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[4]

The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future cash deposits of estimated duties, where applicable. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be equal to the weighted-average dumping margin listed above in the ''Final Results of Review'' section; (2) for merchandise exported by producers or exporters not covered in this review but covered in a previously completed segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published in the final results for the most recent period in which that producer or exporter participated; (3) if the exporter is not a firm covered in this review or in any previous segment of this proceeding, but the producer is, then the cash deposit rate will be that established for the producer of the merchandise in these final results of review or in the final results for the most recent period in which that producer participated; and (4) if neither the exporter nor the producer is a firm covered in this review or in any previously completed segment of this proceeding, then the cash deposit rate will be 11.80 percent *ad valorem,* the all-others rate established in the less than fair value investigation.[5] 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 POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice is the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h).

Dated: January 12, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–00957 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–DS–P

[4] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[5] *See Order,* 80 FR 39996.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–842, A–570–022, C–570–023, A–560–828, C–560–829]

Certain Uncoated Paper From Brazil, the People's Republic of China, and Indonesia: Affirmative Final Determinations of Circumvention of the Antidumping Duty Orders and Countervailing Duty Orders for Certain Uncoated Paper Rolls; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On December 14, 2021, the Department of Commerce (Commerce) published the **Federal Register** notice of the final determination in the anti-circumvention inquiries of the antidumping duty (AD) orders on certain uncoated paper from Brazil, the People's Republic of China (China), and Indonesia and the countervailing duty (CVD) orders on certain uncoated paper from China and Indonesia. This notice inadvertently did not address Commerce's intent to instruct U.S. Customs and Border Protection (CBP) to liquidate certain uncoated paper entries from China.

FOR FURTHER INFORMATION CONTACT: Rachel Greenberg, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1110.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 14, 2021, in FR Doc 2021–26996, on page 71027, in the section titled ''Liquidation of Entries,'' between the second and third paragraph, include the following:

For all entries of merchandise subject to the AD order on uncoated paper from China, entered or withdrawn from warehouse for consumption on or after October 18, 2019, through February 28, 2021, Commerce intends to instruct CBP to liquidate those entries at the applicable AD rates for those entries.[1] For all entries of merchandise subject to the CVD order on uncoated paper from China, entered or withdrawn from warehouse for consumption on or after October 18, 2019, through December 31,

[1] Commerce is not conducting an administrative review of the AD order on uncoated paper from China for the period ending on February 28, 2021. Therefore, Commerce will instruct CBP to liquidate all entries through the end of the last administrative review period.

2020, Commerce intends to instruct CBP to liquidate those entries at the applicable CVD rates for those entries.[2]

Background

On December 14, 2021, Commerce published in the **Federal Register** the final determinations in the circumvention inquiries of the AD orders on certain uncoated paper from Brazil, China, and Indonesia and the CVD orders on certain uncoated paper from China and Indonesia.[3] In the *Final Determination,* we inadvertently did not address Commerce's intent to instruct CBP to liquidate certain entries of uncoated paper from China. This notice serves to correct the ''Liquidation of Entries'' section of the *Final Determination.* No other changes have been made to the *Final Determination.*

Notification to Interested Parties

This determination is issued and published in accordance with section 781(a) of the Tariff Act of 1930, as amended, and 19 CFR 351.225(g).

Dated: January 13, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–00946 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB670]

South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a meeting of the South Atlantic Fishery Management Council's Private Recreational Reporting Workgroup.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a webinar meeting of its Workgroup evaluating reporting alternatives for the private recreational snapper grouper fishery.

DATES: The Workgroup meeting will be held on Wednesday, February 9, 2022, from 1 p.m. until 5 p.m., Eastern.

ADDRESSES: The meeting will be held via webinar. Webinar registration is required. Details are included in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including the webinar registration link, agenda, and briefing book materials will be posted on the Council's website at *https://safmc.net/safmc-meetings/other-meetings/.*

At this meeting the Workgroup will review discussions from its prior meetings and develop recommendations for consideration by the Council.

Written comments may be submitted electronically via the Council's website at *https://safmc.net/safmc-meetings/other-meetings/.* Comments become part of the Administrative Record of the meeting and will automatically be posted to the website and available for Council consideration.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 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: January 13, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–00916 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB695]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, January 20, 2022, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/4233094897902439950.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will consider recommendations from the Recreational Advisory Panel, discuss and develop recommendations to the Council on fishing year 2022 recreational measures for Gulf of Maine cod and Gulf of Maine haddock. They will also receive an overview of the 2021 data and assessment prospects and management workshops. The Committee will receive an overview of progress to date on the Atlantic Cod Research Track Working Group. They will receive an overview of the Council's groundfish priorities for 2022. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has

[2] Commerce is not conducting an administrative review of the CVD order on uncoated paper from China for the period ending on December 31, 2020. Therefore, Commerce will instruct CBP to liquidate all entries through the end of the last administrative review period.

[3] *See Certain Uncoated Paper from Brazil, the People's Republic of China, and Indonesia: Affirmative Final Determinations of Circumvention of the Antidumping Duty Orders and Countervailing Duty Orders for Certain Uncoated Paper Rolls,* 86 FR 71025 (December 14, 2021) (*Final Determination*).

been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: January 13, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–00914 Filed 1–13–22; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB700]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Skate Committee and Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Wednesday, January 19, 2022, at 9 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/5357220193155347979.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Skate Committee and Advisory Panel will recommend preferred alternatives for this action that proposes to update the Northeast Skate Complex FMP objectives and revise the characteristics of the Federal skate permit in Framework Adjustment 9 to the Northeast Skate Complex Fishery Management Plan. Other business may be discussed, as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: January 13, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–00919 Filed 1–13–22; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB694]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Recreational Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Tuesday, January 18, 2022, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/8113101008021066509.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Groundfish Recreational Advisory Panel will discuss and develop recommendations to the Groundfish Committee on fishing year 2022 recreational measures for Gulf of Maine cod and Gulf of Maine haddock. The Panel will also receive an overview of the Council's groundfish priorities for 2022. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: January 13, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–00913 Filed 1–13–22; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB723]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of seminar series presentation.

SUMMARY: The South Atlantic Fishery Management Council (Council) will host a presentation on working waterfront infrastructure in Georgia via webinar.

DATES: The webinar presentation will be held on Tuesday, February 8, 2022, from 1 p.m. until 2:30 p.m.

ADDRESSES:

Meeting address: The presentation will be provided via webinar. The webinar is open to members of the public. Information, including a link to webinar registration will be posted on the Council's website at: *https://safmc.net/safmc-meetings/other-meetings/* as it becomes available.

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, SAFMC; phone: (843) 302–8439 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council will host a presentation from Georgia Southern University on working waterfronts in Georgia. The presentation will describe available fishing infrastructure in Georgia and the industry members utilizing that infrastructure. Information for the project was collected through a census of historic and current industry infrastructure, case studies, spatial analysis, a survey of seafood industry participants, and in-depth interviews. A question-and-answer session will follow the presentation. Members of the public will have the opportunity to participate in the discussion. The presentation is for informational purposes only and no management actions will be taken.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 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: January 13, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–00907 Filed 1–18–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Uniform Formulary Beneficiary Advisory Panel; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Uniform Formulary Beneficiary Advisory Panel (UFBAP) will take place.

DATES: Open to the public on day 1 of the meeting Tuesday, January 25, 2022, 10:00 a.m.–6:00 p.m. and on Day 2 of the meeting January 26, 2022, 9:00 a.m.–6:00 p.m. (Eastern Standard Time).

ADDRESSES: The meeting will be held telephonically or via conference call. The phone number for the remote access on January 25–26, 2022 is: CONUS: 1–888–946–3815; OCONUS: 1–415–228–4881; PARTICIPANT CODE: 6978956.

These numbers and the dial-in instructions will also be posted on the Uniform Formulary Beneficiary Advisory Panel website at: *https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/Beneficiary-Advisory-Panel.*

FOR FURTHER INFORMATION CONTACT: Colonel Paul J. Hoerner, USAF, 703–681–2890 (Voice), *dha.ncr.j-6.mbx.baprequests@mail.mil* (Email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101. Website: *https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/Beneficiary-Advisory-Panel.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense and the Designated Federal Officer, the UFBAP was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its January 25 through 26, 2022 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement. This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix) and 41 CFR 102–3.140 and 102–3.150. The Panel will review and comment on recommendations made to the Director, Defense Health Agency, by the Pharmacy and Therapeutics Committee, regarding the Uniform Formulary.

Purpose of the Meeting: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Uniform Formulary Beneficiary Advisory Panel will take place.

Agenda Items

1. Day 1—January 25, 2022

a. 10:00 a.m.–10:10 a.m. Sign In for UFBAP members

b. 10:10 a.m.–10:20 a.m. Welcome and Opening Remarks by Col Paul J. Hoerner, Designated Federal Officer (DFO), UFBAP

c. 10:20 a.m.–10:30 a.m. Introduction of UFBAP Members by Col Hoerner

d. 10:30 a.m.–10:45 a.m. Opening Remarks by UFBAP Co-Chair Senior Chief Petty Officer (Ret) Jon R. Ostrowski, Non-Commissioned Officers Association

e. 10:45 a.m.–11:00 a.m. Introductory Remarks by CDR Scott Raisor, Interim Chief, Formulary Management Branch

2. Discussion of the February 2021 DoD P&T Committee Recommendations

Scheduled Therapeutic Class Reviews

a. 11:00 a.m.–11:30 a.m. Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors (LCDR Todd Hansen)

b. 11:30 a.m.–12:00 p.m. Pulmonary III Agents (Dr. Angela Allerman)

c. 12:00 p.m.–1:00 p.m. Break for Lunch

d. 1:00 p.m.–1:45 p.m. Newly Approved Drugs Review (Dr. Amy Lugo, and other FMB staff, including CDR Raisor, and MAJ Adam Davies)

e. 1:45 p.m.–2:45 p.m. Pertinent Utilization Management Issues (MAJ Davies, and other FMB staff, including Dr. Allerman, and CDR Raisor)

* Note that the UFBAP Discussion and Vote will follow each section

f. 2:45 p.m.–3:00 p.m. Break

3. Discussion of the May 2021 DoD P&T Committee Recommendations

Scheduled Therapeutic Class Reviews

a. 3:00 p.m.–3:30 p.m. Menopausal Hormone Therapy: Single Agents, Combination Agents, and Vaginal Agents (LCDR Elizabeth Hall)
b. 3:30 p.m.–4:00 p.m. Sleep Disorders: Insomnia (Dr. Lugo)
c. 4:00 p.m.–4:45 p.m. Newly Approved Drugs Review (Dr. Lugo, and other FMB staff including, LCDR Hall, MAJ Davies, LCDR Hansen, and Dr. Allerman)
d. 4:45 p.m.–5:15 p.m. Pertinent Utilization Management Issues (MAJ Davies and other FMB staff including Dr. Allerman, Dr. Lugo, and LCDR Hall)
e. 5:15 p.m.–5:30 p.m. Re-evaluation of Nonformulary generics (Dr. Allerman)
* Note that the UFBAP Discussion and Vote will follow each section
f. 5:30 p.m.–5:45 p.m. Closing Remarks by Senior Chief Petty Officer (Ret) Ostrowski
g. 5:45 p.m.–6:00 p.m. Closing Remarks by Col Hoerner

Agenda Items

1. Day 2—January 26, 2022

a. 9:00 a.m.–9:10 a.m. Sign In for UFBAP members
b. 9:10 a.m.–9:15 a.m. Welcome and Opening Remarks by Col Hoerner
c. 9:15 a.m.–9:30 a.m. Opening Remarks by Senior Chief Petty Officer (Ret) Ostrowski

2. Discussion of the August 2021 DoD P&T Committee Recommendations

Scheduled Therapeutic Class Reviews

a. 9:30 a.m.–10:00 a.m. Leukemia and Lymphoma Agents, Burton Tyrosine Kinase Inhibitors LCDR Hansen)
b. 10:00 a.m.–10:30 a.m. Laxative-Cathartics-Stool Softeners—Bowel Preparations (Dr. Lugo)
c. 10:30 a.m.–10:45 a.m. Break
d. 10:45 a.m.–11:45 a.m. Newly Approved Drugs Review (Dr. Lugo and other FMB staff, including LCDR Hall, LCDR Hansen, Dr. Allerman, CDR Raisor, and MAJ Davies)
e. 11:45 a.m.–12:45 p.m. Pertinent Utilization Management Issues (MAJ Davies and other FMB staff, including Dr. Lugo, and CDR Raisor)
f. 12:45 p.m.–1:00 p.m. Tier Co-Payment Change for the Pulmonary III Agents (CDR Raisor)
g. 1:00 p.m.–1:15 p.m. Brand over Generic Authorization and Tier 1 Co-Payment Change for the Pulmonary Arterial Hypertension Drugs (Dr. Allerman)
* Note that the UFBAP Discussion and Vote will follow each section
h. 1:15 p.m.–2:15 p.m. Break for Lunch

3. Discussion of the November 2021 DoD P&T Committee Recommendations

Scheduled Therapeutic Class Reviews

a. 2:15 p.m.–3:00 p.m. Continuous Glucose Monitoring Systems—Therapeutic Agents (Dr. Lugo)
b. 3:00 p.m.–3:30 p.m. Immunological Agents Miscellaneous—Subcutaneous Immunoglobulins (LCDR Hansen)
c. 3:30 p.m.–4:30 p.m. Newly Approved Drugs Review (Dr. Lugo and other FMB staff including LCDR Hansen, LCDR Giao Phung, LCDR Hall, MAJ Davies and Maj Angelina Escano)
d. 4:30 p.m.–4:45 p.m. Break
e. 4:45 p.m.–5:45 p.m. Pertinent Utilization Management Issues (MAJ Davies)
*Note that the UFBAP Discussion and Vote will follow each section
f. 5:45 p.m.–5:55 p.m. Closing Remarks by Senior Chief Petty Officer (Ret) Ostrowski
g. 5:55 p.m.–6:00 p.m. Closing Remarks by Col Hoerner

Meeting Accessibility: Pursuant to section 10(a)(1) of the FACA and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of phone lines, this meeting is open to the public. Telephone lines are limited and available to the first 220 people dialing in. There will be 220 line total: 200 domestic and 20 international, including leader lines.

Written Statements: Pursuant to 41 CFR 102–3.10, and section 10(a)(3) of FACA, interested persons or organizations may submit written statements to the Uniform Formulary Beneficiary Advisory Panel about its mission and/or the agenda to be addressed in this public meeting. Written statements should be submitted to the Uniform Formulary Beneficiary Advisory Panel's Designated Federal Officer (DFO). The DFO's contact information can be found in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Written comments or statements must be received by the Uniform Formulary Beneficiary Advisory Panel's DFO at least two (2) calendar days prior to the meeting so they may be made available to the Uniform Formulary Beneficiary Advisory Panel for its consideration prior to the meeting. The DFO will review all submitted written statements and provide copies to all Uniform Formulary Beneficiary Advisory Panel members.

Dated: January 12, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2022–00887 Filed 1–18–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Request for Nominations: National Committee on Foreign Medical Education and Accreditation (NCFMEA)

AGENCY: Department of Education, National Committee on Foreign Medical Education and Accreditation (NCFMEA).

ACTION: Request for nominations for appointment to serve on the National Committee on Foreign Medical Education and Accreditation (NCFMEA).

SUMMARY: Secretary of Education, Miguel A. Cardona, Ed.D., is seeking nomination(s) of medical experts for appointment to fill six vacant positions for service as a member of the National Committee on Foreign Medical Education and Accreditation (NCFMEA).

DATES: Nominations must be received no later than Friday, February 18, 2022.

SUPPLEMENTARY INFORMATION: NCFMEA's Statutory Authority and Function: The NCFMEA is authorized per section 102 of the Higher Education Act of 1965, as amended. The Secretary of Education is required by the Higher Education Act, as amended, to establish a panel of medical experts who shall: Evaluate the standards of accreditation applied to foreign medical schools; and determine the comparability of those standards to standards for accreditation applied to United States medical schools. The NCFMEA shall be comprised of 11 voting members each appointed for a term of service as determined by the Secretary of Education. Due consideration shall be given to the appointment of individuals who are broadly knowledgeable about foreign medical education and accreditation and respected in the educational community. Per the authorizing legislation for the Committee, one currently serving member of the NCFMEA, is a medical student enrolled in an accredited medical school at the time of appointment by the Secretary of Education.

Any member appointed to fill a vacancy for a term of service not completed will serve for the remainder of the term of service of her/his predecessor. No member may serve for a period in excess of three consecutive terms. Members of the Committee will serve as Special Government Employees (SGEs), as defined in 18 U.S.C. 202(a). As SGEs, members are selected for their individual expertise, integrity, impartiality, and experience.

Nomination Process: Interested persons, stakeholders, or organizations (including individuals seeking reappointment by the Secretary of Education to serve on the NCFMEA) may nominate a qualified medical expert(s). To submit a nomination(s) or self-nominate for appointment to serve on the NCFMEA, please send a cover letter addressed to the Secretary of Education as follows: Honorable Miguel A. Cardona, Ed.D., Secretary of Education, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. In the letter, please note your reason(s) for submitting the nomination. Include a copy of the nominee's current resume/cv and contact information (nominee's name, mailing address, email address, and contact phone number). In addition, the cover letter must include a statement affirming that the nominee (if you are nominating someone other than yourself) has agreed to be nominated and is willing to serve on the NCFMEA if appointed by the Secretary of Education. Please submit your nomination(s) including the requested attachments to the U.S. Department of Education, Office of the Secretary, Committee Management via email to: *cmtemgmtoffice@ed.gov*. (Please specify in the email subject line ''NCFMEA Nomination'').

For questions, please contact Karen Akins, U.S. Department of Education, Committee Management Officer, Office of the Secretary, (202) 401–3677, or via email at *Karen.Akins@ed.gov*.

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**.

Miguel A. Cardona,

Secretary of Education.

[FR Doc. 2022–00908 Filed 1–18–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Building a Better Grid Initiative To Upgrade and Expand the Nation's Electric Transmission Grid To Support Resilience, Reliability, and Decarbonization

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of intent.

SUMMARY: In this notice, the Department of Energy (DOE or the Department) unveils its new Building a Better Grid Initiative focused on catalyzing nationwide development of new and upgraded high-capacity transmission lines. Under the Building a Better Grid Initiative, DOE will identify critical national transmission needs and support the buildout of long-distance, high-voltage transmission facilities that meet those needs through collaborative transmission planning, innovative financing mechanisms, coordinated permitting, and continued transmission related research and development. DOE commits to robust engagement on energy justice and collaboration, including with states, American Indian Tribes and Alaska Natives, industry, unions, local communities, and other stakeholders for successful implementation of the program.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle Manary, Acting Deputy Assistant Secretary, Electricity Delivery Division, Office of Electricity, Mailstop OE–20, Room 8H–033, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (202) 586–1411 or *ElectricityDelivery@hq.doe.gov.* More information will also be available at *https://www.energy.gov/oe/office-electricity.*

SUPPLEMENTARY INFORMATION:

I. Background

A robust transmission system is critical to the Nation's economic, energy, and national security. However, the United States faces challenges as its electric grid infrastructure continues to age—studies from the past decade find that 70 percent of the grid's transmission lines and power transformers were over 25 years old.[1] [2] In addition, insufficient transmission capacity—especially transmission that facilitates transfer of power across regions—presents another critical challenge facing the grid. Upgrading and expanding the current transmission system will enhance grid reliability and resilience and enable the cost-effective integration of clean energy.

Modernizing, hardening, and expanding the grid will enhance the resilience of our entire electric system, and ensure that electricity is available to customers when it is needed most. Aging infrastructure leaves the grid increasingly vulnerable to attacks.[3] The increasing frequency of extreme weather events is leading to energy supply disruptions that threaten the economy, put public health and safety at risk, and can devastate affected communities all over the country. Investment in transmission infrastructure can help protect the grid against supply disruptions due to physical and cyber-attacks or climate-induced extreme weather, minimize the impact of supply disruptions when they happen, and restore electricity more quickly when outages do occur.

Expanding transmission capacity also improves reliability by creating stronger and more numerous energy delivery pathways, helping to ensure that consumers have a dependable source of electricity to power their homes, schools, and businesses. When one generation source is physically unavailable or uneconomic, transmission enables delivery from other generation sources, making the system better equipped to meet delivery requirements under the broader range of real circumstances and stresses seen in recent years.

Electric grid investment also spurs economic growth. Investment in the grid will create demand for well-paying jobs in construction and will drive innovation, commercialization, and deployment of energy technologies that can spur new businesses. Moreover, clean energy generation is increasingly the least-cost option in many parts of the country, and investment in transmission will play a critical role in unlocking the deployment of greater renewable energy generation.

Transmission is critical to addressing the climate crisis through the decarbonization of the power sector and electrification of transportation and other sectors. The climate crisis accelerates the need for the United States to modernize its electric grid. To

[1] *See* U.S. Dep't of Energy, Infographic: Understanding the Grid (Nov. 2014), *https://www.energy.gov/articles/infographic-understanding-grid.*

[2] *See* Energy Information Agency, *Major utilities continue to increase spending on U.S. electric distribution systems,* (July 20, 2018), *https://www.eia.gov/todayinenergy/detail.php?id=36675.*

[3] *See* ICF International, *Electric Grid Security and Resilience: Establishing a Baseline for Adversarial Threats,* at 26 (June 2016), *https://www.energy.gov/sites/prod/files/2017/01/f34/Electric%20Grid%20Security%20and%20Resilience—Establishing%20a%20Baseline%20for%20Adversarial%20Threats.pdf.*

address the imminent threat of climate change, and capitalize on the economic opportunity of doing so, President Biden established ambitious goals: A carbon pollution-free power sector by 2035, and a net-zero greenhouse gas emissions economy by 2050.[4] Multiple pathways exist for the United States to meet these clean energy goals, but all require upgrading and expanding the Nation's transmission infrastructure.[5] In particular, they require deploying interstate high-voltage lines connecting areas with significant renewable energy resources to demand centers and linking together independently operated grid regions. The most cost-effective renewable resources are often located in remote geographic areas far from the areas with the biggest demand.[6] Therefore, accelerating the shift toward a clean power sector requires investment in critical enabling infrastructure such as transmission to increase access to these renewable energy sources.[7] Numerous studies conclude ''that a reliable power system that depends on very high levels of renewable energy will be impossible to implement without doubling or tripling the size and scale of the [N]ation's transmission system.'' [8] A recent study found as the number of generation and storage projects proposed for interconnection to the bulk-power system is growing, interconnection queue wait times are increasing and the percentage of projects reaching completion appears to be declining, particularly for wind and solar resources.[9] Needed investments in transmission infrastructure include increasing the capacity of existing lines, using advanced technologies to minimize transmission losses and maximize the value of existing lines, and building new long-distance, high-voltage transmission lines.

Recognizing these challenges, Congress enacted and the President signed the Infrastructure Investment and Jobs Act (IIJA) on November 15, 2021. IIJA builds on existing Department of Energy authorities to provide substantial new tools and funding to the Department to accelerate the modernization, expansion, and resilience of the Nation's electric grid. DOE intends to coordinate the use of all authorities and funding focused on collaborative planning, innovative financing mechanisms, and coordinated permitting now at the disposal of the Department to resolve challenges and constrains facing the electric grid.

II. Transmission Deployment Program

For the reasons discussed previously, DOE intends to launch a coordinated transmission deployment program to implement both IIJA and previously enacted authorities and funding. Under the Building a Better Grid Initiative, DOE will engage in a collaborative initiative to encourage and enable investment in transmission infrastructure. DOE recognizes the importance of engaging with other federal agencies, state and local governments, American Indian Tribes and Alaska Natives, industry, unions, local communities, environmental justice organizations, and other stakeholders. Working with these partners, DOE aims to increase coordination and transparency; to employ available tools and resources to support the development of nationally-significant transmission projects; and to improve transmission siting, permitting, and authorization processes.

DOE's implementation of the Building a Better Grid Initiative will fall into five broad categories: Coordination; enhancing transmission planning to identify areas of greatest need; deploying federal financing tools to reduce project development risk; facilitating an efficient transmission permitting process; and performing transmission-related research and development.

A. Coordination

Early and collaborative engagement is an essential element of building a reliable, resilient, and efficient electric grid. DOE will consult and work collaboratively with government entities, including states, American Indian Tribes, and Alaska Natives, and other stakeholders throughout the process of evaluating and deploying the Department's tools and authorities to accelerate transmission deployment.

(1) *Regional Convenings.* In most of the country, the primary venue in which the future of the transmission grid is being planned is through regional and state-level processes led by transmission planning organizations such as independent system operators (ISOs)/regional transmission organizations (RTOs), state regulatory commissions, and utilities, with key involvement from transmission developers, independent power producers, consumer advocates, unions, public interest organizations, technology providers, and other stakeholders that contribute to the planning process to identify where and when new transmission lines are needed to ensure that the delivery of electricity remains reliable and affordable. In implementing the specific elements of the Building a Better Grid initiative described underneath, DOE intends to leverage existing regional venues where stakeholders are convened around transmission planning to identify nationally significant transmission lines, validate transmission modeling approaches, and provide technical analysis to states, American Indian Tribes and Alaska Natives, ISOs/RTOs, and utilities.

(2) *Offshore Wind Transmission Convening.* DOE is partnering with the Department of the Interior's Bureau of Ocean Energy Management (BOEM) to convene key stakeholders, government partners, and ocean users, including American Indian Tribes and Alaska Natives, state and local governments, ISOs/RTOs, utilities, wind energy developers, and non-governmental organizations, to elucidate the central transmission challenges associated with meeting the Biden Administration's goal—30 GW of deployed offshore wind (OSW) capacity by 2030 and to facilitate OSW development well beyond that goal—and identify potential solutions to those challenges. Later this year, DOE and BOEM will lead a series of convening workshops, in consultation with the Federal Energy Regulatory Commission (FERC) and other federal agencies, to develop a set of recommendations and associated action plan for addressing medium- and long-term OSW transmission challenges. These will include recommendations for OSW transmission development, transmission planning and permitting policies, as well as seeking to maximize benefits to the onshore transmission system by considering solutions that will reduce congestion and support system interconnection inclusive of

[4] *See* Executive Order 14008 of Jan. 27, 2021, Tackling the Climate Crisis at Home and Abroad, 86 FR 7619 (Feb. 1, 2021), *https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad; Fact Sheet: President Biden Sets 2030 Greenhouse Gas Pollution Reduction Target Aimed at Creating Good-Paying Union Jobs and Securing U.S. Leadership on Clean Energy Technologies* (Apr. 22, 2021), *https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/22/fact-sheet-president-biden-sets-2030-greenhouse-gas-pollution-reduction-target-aimed-at-creating-good-paying-union-jobs-and-securing-u-s-leadership-on-clean-energy-technologies/.*

[5] *See North American Renewable Integration Study, Executive Summary, p. 9.*

[6] *See id.* at 4–5.

[7] *See* Eric Larson, et al., *Net-Zero America: Potential Pathways, Infrastructure, and Impacts,* at 13–14 (Dec. 15, 2020), *https://netzeroamerica.princeton.edu/img/Princeton_NZA_Interim_Report_15_Dec_2020_FINAL.pdf.*

[8] ESIG Report at 10 (providing a summary of six studies at Appendix B); also, see *Net Zero America* (previous footnote).

[9] *See* Joseph Rand, et al., *Queued Up: Characteristics of Power Plants Seeking Transmission Interconnection as of the End of 2020,* Briefing at 6 (May 2021), *https://eta-publications.lbl.gov/sites/default/files/queued_up_may_2021.pdf.*

potential onshore transmission upgrades.

B. Planning

Building a cost-effective transmission network that offers access to a diversity of energy resources within and across geographic regions, and that supports reliability and resilience through robust inter-regional transfer capability, requires deliberate planning and a different approach than has been used traditionally. Transmission planning processes have not generally been designed to identify long-term (beyond 10-year planning cycles), flexible, and inter-regional solutions that will meet national interests by enhancing electric system resilience across regions. Modernizing transmission planning can provide greater certainty to drive investment to the highest-need transmission projects and enable development of the projects with the largest long-term benefit for consumers. DOE intends to consider the following actions to facilitate transmission planning:

(1) *National Transmission Needs Study.* DOE intends to identify high-priority national transmission needs—specifically, to identify where new or upgraded transmission facilities could relieve expected future constraints and congestion driven by deployment of clean energy consistent with federal, state, and local policy and consumer preferences; higher electric demand as a result of building and transportation electrification; and insufficient transfer capacity across regions—by conducting a Transmission Needs Study. Consistent with authority provided by the Energy Policy Act of 2005 [10] and the IIJA, this study will evaluate current and expected future electric transmission capacity constraints and congestion that could adversely affect consumers. DOE will consult with affected states, American Indian Tribes and Alaska Natives, and appropriate regional entities. The results of this needs assessment can inform the prioritization of the DOE financing authorities described in Section II.C of this document; designation of national interest electric transmission corridors (National Corridors), as described in Section II.D of this document, and regional transmission planning processes.

(2) *National Transmission Planning.* In addition to the Transmission Needs Study, DOE is leading a national-scale, long-term (a 15- to 30-year) transmission planning analysis to identify transmission that will provide broad-scale benefits to electric customers; inform regional and interregional transmission planning processes; and identify interregional and national strategies to accelerate decarbonization while maintaining system reliability. In partnership with the Pacific Northwest National Laboratory (PNNL) and the National Renewable Energy Laboratory (NREL), DOE will work with stakeholders to help identify viable future grid realization pathways to a large-scale transmission system buildout that would accomplish clean energy goals. Robust stakeholder engagement will help define new scenarios for analysis to reach grid decarbonization goals cost effectively and under new high-stress conditions. As part of this process, DOE intends to work with the Department of Transportation, the Department of the Interior, the United States Forest Service, other federal and state agencies, and utilities as appropriate, to integrate existing rights-of-way into the National Transmission Planning Study, including existing rail and highway rights-of-way; the Bureau of Land Management's (BLM) West-wide Energy Corridors; and other existing federal land and utility rights-of-way.

(3) *OSW Transmission Analysis.* To inform the integration of OSW, DOE will conduct supportive analyses to identify transmission pathways and develop transmission strategies to integrate offshore wind, consistent with the Administration's goal of 30 GW of OSW by 2030 and to set the stage for a more ambitious 2050 OSW deployment target. In November 2021, DOE launched the Atlantic Offshore Wind Transmission Study, a 2-year study led by NREL and PNNL. Through robust engagement with diversified stakeholder groups, this work evaluates coordinated transmission solutions to enable offshore wind energy deployment along the U.S. Atlantic Coast, addressing gaps in existing analyses.[11]

(4) *Transmission Planning Technical Assistance.* DOE will continue to develop and leverage modeling tools and capabilities to provide technical analysis to states and regions, and other agencies, where appropriate. This includes the research and capabilities created as part of the National Transmission Planning and the OSW Transmission Analysis above. The technical analysis and assistance aim to aid in long-term energy planning, policy implementation, and regulatory rulemaking, informed by core transmission planning precepts and in alignment with current federal and state public policy goals. The IIJA requires states to incorporate transmission planning as a mandatory feature of their energy plans and is supported with $500 million in increased funding for the State Energy Program.

C. Financing

Financial risk poses a significant barrier to pursuing large scale, multi-region transmission projects. Transmission projects require large, upfront investments. For regulated utility projects, returns are ultimately collected over long periods through rates charged to end-use customers, but it is difficult for such utilities to recover costs for transmission projects that cross multiple service territories and planning regions. Merchant transmission developers face challenges securing transmission customers before a project is built, but customer commitments are often needed to reduce investment risk. The IIJA provided critical new authorities and appropriations that the Department can use to help reduce financing challenges project sponsors may face and catalyze private investment in transmission. DOE intends to deploy these authorities while also continuing to make available existing financing tools.

New Programs Authorized in IIJA:

(1) *Transmission Facilitation Program.* The IIJA establishes a new $2.5B revolving fund to facilitate the construction of high capacity new, replacement, or upgraded transmission lines.[12] This program will prioritize projects that improve resilience and reliability of the grid, facilitate inter-regional transfer of electricity, lower electric sector greenhouse gas emissions, and use advanced technology. DOE is authorized to do so through three separate tools.

- DOE is authorized to serve as an anchor customer on new and upgraded transmission lines in order to facilitate the private financing and construction of the line. Under this authority, DOE would buy up to 50 percent of planned capacity from the developer for a term of up to 40 years. A purchase of capacity will not be considered a ''major federal action'' that would trigger environmental review pursuant to the National Environmental Policy Act (NEPA). DOE will then market the capacity it has purchased to recover the

[10] Federal Power Act (FPA) section 216(a); 16 U.S.C. 824p(a).

[11] *See* Atlantic Offshore Wind Transmission Study, NREL. *https://www.nrel.gov/wind/atlantic-offshore-wind-transmission-study.html.*

[12] In addition, eligible projects include those that would connect an isolated microgrid to an existing transmission, transportation, or infrastructure corridor located in Alaska, Hawaii, or a U.S. territory.

costs it has incurred once the project's long-term financial viability is secured.

- DOE is authorized to make loans for the cost of carrying out eligible transmission projects.
- DOE is authorized to enter into public-private partnerships to co-develop projects that are located in a National Corridor or that are necessary to accommodate an increase in demand for interstate transmission, among other criteria. Such co-development can entail the design, development, construction, operation, maintenance, or ownership of a project.

DOE intends to establish procedures for the administration of this program and for solicitation and selection of project applications. Further guidance will be forthcoming for this program.

(2) *Enhancing Grid Resilience.* DOE will provide formula grants, competitive grants, and competitive awards across a number of provisions of the IIJA that allow for upgrading transmission infrastructure. DOE intends to issue solicitations for applications by states, American Indian Tribes, local communities, and industry. Further guidance and solicitations will be forthcoming for these programs.

- Preventing Outages and Enhancing the Resilience of the Electric Grid—The IIJA authorizes DOE to make grants for supplemental hardening activities to reduce risks of power lines causing wildfires, and the likelihood and consequence of impacts to the electric grid due to extreme weather, wildfires, and natural disasters. This program is split between $2.5 billion in matching grants for industry and $2.5 billion in formula grants for states and American Indian tribes.
- Program Upgrading Our Electric Grid and Ensuring Reliability and Resiliency—The IIJA authorizes DOE to provide $5 billion in competitive financial assistance to states, local governments, and American Indian tribes. This financial assistance must support electric sector owners and operators with projects that demonstrate innovative approaches to hardening and enhancing the resilience and reliability of transmission, storage, and distribution infrastructure.
- Energy Improvement in Rural and Remote Areas—DOE is authorized to provide competitive grants to small cities, towns, and unincorporated areas to improve resilience, safety, reliability, and availability of energy; and that provide environmental protection from adverse impacts of energy generation.

(3) *Deployment of Technologies to Increase Capacity and Enhance Flexibility of the Existing Grid.* The IIJA provides DOE with $3 billion to provide matching grants for the deployment of advanced grid technologies to enhance grid flexibility. Building on the success of the Smart Grid Investment Grant Program, this program now includes advanced transmission technologies such as dynamic line rating, flow control devices, advanced conductors, and network topology optimization, to increase the operational transfer capacity transmission networks. Further guidance and solicitations will be forthcoming for this program.

Existing DOE Programs:

(4) *Loan Programs.* DOE's Loan Programs Office (LPO) administers a number of programs that can provide loan guarantees to help deploy large-scale energy infrastructure projects in the United States, some of which have already been utilized to issue over $300 million in Conditional Commitment for the construction and energization of a new transmission line. Under the Title 17 Innovative Energy Loan Guarantee Program and the Tribal Energy Loan Guarantee Program, the Department is authorized to provide loan guarantees to projects that will expand and improve the transmission grid. Through these programs, LPO can offer borrowers access to debt capital, flexible financing customized for the specific needs of borrowers, and valuable expertise in energy infrastructure project development. LPO can also reduce the risk of investment in long-distance transmission projects by providing financing support for projects that analysis shows are likely to support repayment of the loan, even if those projects have not yet secured pre-construction agreements for transmission service for their full capacity.

(5) *Transmission Infrastructure Program* (TIP). The Western Area Power Administration (WAPA) administers a unique federal infrastructure development assistance and financing program. TIP manages WAPA's statutory $3.25 billion borrowing authority to provide debt financing and development assistance for qualifying transmission projects with at least one terminus in WAPA's 15-state service territory and that facilitate delivery of renewable energy. The program leverages WAPA's transmission project development expertise and WAPA's borrowing authority, partnering with private and other non-federal co-investment to support the development of critical transmission and related infrastructure in the West.

D. Permitting

The siting and permitting of interstate and inter-regional high-voltage transmission generally requires action by many different authorities governing the federal, state, local, and Tribal lands, as well as private lands, that facilities will pass through. Projects involving multiple agencies are subject to a wide array of processes and procedural requirements for compliance with legal mandates and multiple authorizations. The time required to meet these legal mandates can be reduced through effective planning processes that take advantage of existing rights-of-way, which as outlined previously, DOE intends to incorporate into its planning activities. As an example, DOE is coordinating with BLM as the agency updates its designated West-wide Energy Corridors. But where such rights-of-way are not available, siting and permitting processes can significantly slow development and should be conducted efficiently, with clear expectations and predictable timelines and processes. These aims should occur without sacrificing important analysis, protection of environmental, cultural, and other important values, or robust public engagement. DOE intends to coordinate with states and with federal permitting agencies to help facilitate the siting and permitting process, including through consideration of the following actions:

(1) *Federal Permitting Coordination.* The Federal Permitting Improvement Steering Council (FPISC), established pursuant to Title 41 of the Fixing America's Surface Transportation Act (''FAST–41''), and made permanent by IIJA, facilitates coordination and oversight procedures for federal environmental review and permitting process related to eligible large-scale infrastructure projects. IIJA provided additional authority to FPISC to include projects on the permitting dashboard. DOE will work with relevant agencies to evaluate and recommend whether to include nationally-significant transmission projects on the dashboard. In addition, DOE works with interagency partners to bolster pre-application planning for transmission projects through its Integrated Interagency Pre-Application Process, which allows transmission project developers a mechanism for early coordination and information sharing with permitting agencies.[13] DOE intends to encourage developers to take advantage of the pre-application process in order to streamline federal permitting action.

(2) *Public-private partnership projects.* The previously-described Transmission Facilitation Program,

[13] FPA section 216(h); 42 U.S.C. 824p(h).

enacted as part of IIJA, includes authority for the Secretary to enter into public-private partnerships for the design, development, construction, operation, maintenance, and ownership of transmission facilities. In addition, the Secretary, acting through the Administrators of the Southwestern Power Administration (SWPA) or WAPA, has the authority to design, develop, construct, operate, maintain, or own, alone or in partnership with third parties, transmission system upgrades or new transmission lines and related facilities within states in which WAPA and SWPA operate.[14] In exercising these authorities, DOE can help facilitate transmission development in areas where state or local permitting requirements would otherwise make a project difficult or impossible to complete. In carrying out either type of project, the Secretary may accept and use contributed funds from another entity, such as a transmission developer, to carry out the Department's work on upgrades or on new projects. DOE may solicit interest in these public-private partnership projects, with a particular focus on projects that would fulfill transmission needs identified by the transmission planning actions outlined previously.

(3) *Designation of Route-Specific Transmission Corridors.* The Federal Energy Regulatory Commission (FERC) has authority, clarified by the IIJA, to issue permits for the construction or modification of electric transmission facilities in National Corridors designated by the Secretary of Energy.[15] IIJA also clarified that National Corridors can be any area experiencing or expected to experience electricity transmission capacity constraints or congestion that adversely affects consumers.[16] DOE can designate a National Corridor after taking into consideration the Transmission Needs Study discussed previously and other information. In order to facilitate the efficient consideration of projects seeking a FERC-issued permit, DOE intends to provide a process for the designation of National Corridors on a route-specific, applicant-driven basis. DOE intends to give particular consideration to proposed National Corridors that, to the greatest degree possible, overlap with or utilize existing highway, rail, utility, and federal land rights-of-way. Further, in order to enable effective use of both DOE's route-specific National Corridor process and FERC's permitting process, DOE and FERC intend to work together, as appropriate, to establish coordinated procedures that facilitate efficient information gathering related to the scope of activities under review pursuant to these authorities. By harmonizing, to the greatest extent practicable, pre-filing and application processes, DOE and FERC can work with applicants to identify and resolve issues as quickly as possible; share information in a timely fashion; and expedite reviews conducted pursuant to these authorities, the National Environmental Policy Act, and other requirements.

E. Transmission Research, Development, and Demonstration (RD&D)

DOE continues to conduct RD&D to further develop and reduce the costs of technologies that enable the transmission system to be used more efficiently, including grid enhancing technologies, improved transmission conductors, and grid-related energy storage facilities. The National Laboratories' research programs, in partnership with industry, are investing in the next generation of components and systems. DOE's FY22 budget request prioritizes solicitations to support transmission technology development including transformers, high voltage direct current converter stations, and storage.

DOE is also developing and improving analytical tools to more effectively support transmission deployment. DOE, in collaboration with several National Laboratories, is developing the North American Energy Resilience Model (NAERM), a national-scale energy planning and real-time situational awareness tool. DOE is working to enable and expand NAERM's capabilities to facilitate effective transmission planning. Currently deployed transmission planning tools include the Energy Zones Mapping Tool, an online mapping tool that can be used to identify potential energy resource areas and energy corridors, and the Transmission Resilience Maturity Model that enables utilities to measure the maturity of their transmission resilience programs and identify improvements to increase the resilience of their transmission systems.

Moving forward, the Department will keep the public informed of its planned activities and progress related to this Building a Better Grid Initiative to expand and improve the Nation's electric transmission grid. DOE is committed to robust engagement and collaboration with states, American Indian Tribes and Alaska Natives, industry, unions, local communities, environmental justice organizations, and other stakeholders. For additional information, interested parties may reach out to DOE's Office of Electricity using the contact information provided in this Notice.

Signing Authority

This document of the Department of Energy was signed on January 11, 2022, by Jennifer M. Granholm, 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 on publication in the **Federal Register**.

Signed in Washington, DC, on January 12, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–00883 Filed 1–18–22; 8:45 am]

BILLING CODE 6450–01–P

[14] Energy Policy Act of 2005 section 1222; 42 U.S.C. 16421.

[15] FPA section 216(b); 16 U.S.C. 824p(b).

[16] Section 216(a) of the FPA; 16 U.S.C. 824p(a).

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual combined meeting of the Consent Order Committee and Risk Evaluation and Management Committee of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Wednesday, February 16, 2022; 1:00 p.m.–4:00 p.m.

ADDRESSES: This meeting will be held virtually via WebEx. To attend, please contact Menice Santistevan by email, *Menice.Santistevan@em.doe.gov*, no later than 5:00 p.m. MT on Friday, February 11, 2022.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board

(NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 699–0631 or Email: *Menice.Santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Purpose of the Consent Order Committee (COC): It is the mission of the COC to review the Consent Order, evaluate its strengths and weaknesses, and make recommendation as to how to improve the Consent Order. It is also within the mission of this committee to review and ensure implementation of NNMCAB Recommendation 2019–02, Improving the Utility of the Consent Order with Supplementary Information. The COC will work with the NNMCAB Risk Evaluation and Management Committee to review the risk-based approaches used to determine the prioritization of cleanup actions, as well as the ''relative risk ranking'' of the campaigns, targets, and milestones by the NNMCAB, to be recommended for use by the DOE EM Los Alamos Field Office (EM–LA) both within and outside of those activities covered by the Consent Order.

Purpose of the Risk Evaluation and Management Committee (REMC): The REMC provides external citizen-based oversight and recommendations to the DOE EM–LA on human and ecological health risk resulting from historical, current, and future hazardous and radioactive legacy waste operations at Los Alamos National Laboratory (LANL). The REMC will, to the extent feasible, stay informed of DOE EM–LA and LANL's environmental restoration and long-term environmental stewardship programs and plans. The REMC will also work with the NNMCAB COC to provide DOE EM–LA and LANL with the public's desires in determining cleanup priorities. The REMC will prepare recommendations that represent to the best of committee's knowledge and ability to determine, the public's position on human and ecological health risk issues pertaining to direct radiation or contaminant exposure to soils, air, surface and groundwater quality, or the agricultural and ecological environment.

Tentative Agenda:

- Approval of Agenda
- Old Business
- New Business
- Preparation of NNMCAB Work Plan
- Public Comment Period
- Update from Deputy Designated Federal Officer

Public Participation: The online virtual meeting is open to the public. To sign up for public comment, please contact Menice Santistevan by email, *Menice.Santistevan@em.doe.gov*, no later than 5:00 p.m. MT on Friday, February 11, 2022. Written statements may be filed with the Committees either before or within five days after the meeting by sending them to Menice Santistevan at the aforementioned email address. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by emailing or calling Menice Santistevan at the email address or telephone number listed above. Minutes and other Board documents are on the internet at: *https://energy.gov/em/nnmcab/meeting-materials.*

Signed in Washington, DC, on January 12, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–00903 Filed 1–18–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meetings

TIME AND DATE: January 20, 2022, 10 a.m.

PLACE: Open to the public via audio Webcast only. Join FERC online to listen live at *http://ferc.capitolconnection.org/.*

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* *Note*—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

1086TH—MEETING

[Open Meeting; January 20, 2022, 10 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD22–1–000	Agency Administrative Matters.
A–2	AD22–2–000	Customer Matters, Reliability, Security and Market Operations.
	Electric	
E–1	RM22–3–000	Internal Network Security Monitoring for High and Medium Impact Bulk Electric System Cyber Systems.
E–2	ER19–105–005	PJM Interconnection, L.L.C.
E–3	ER22–461–000; ER22–462–000	Midcontinent Independent System Operator, Inc.
E–4	ER22–474–000	Talen Energy Marketing, LLC.
	ER22–539–000	EF Kenilworth LLC.
	ER22–550–000	Chambersburg Energy, LLC.
	ER22–551–000	Rockford Power, LLC.
	ER22–552–000	Rockford Power II, LLC.
	ER22–553–000	Troy Energy, LLC.
	ER22–554–000	LSP University Park, LLC.
	ER22–555–000	University Park Energy, LLC.
	ER22–681–000	Exelon Generation Company, LLC.

1086TH—MEETING—Continued

[Open Meeting; January 20, 2022, 10 a.m.]

Item No.	Docket No.	Company
	ER22–704–000 (not consolidated)	Energy Center Dover, LLC and Monitoring Analytics, LLC.
	EL22–22–000	PJM Interconnection, L.L.C.
E–5	ER20–1828–000; ER20–1828–001; ER20–1828–002.	PacifiCorp.
E–6	ER21–2778–000	UGI Corporation.
E–7	ER20–1832–001	PJM Interconnection, L.L.C., Duke Energy Ohio, Inc., and Duke Energy Kentucky, Inc.
E–8	ER21–1215–002	Assembly Solar I, LLC.
E–9	ER20–2541–001	Entergy Louisiana, LLC.
E–10	ER22–448–000	Northern Indiana Public Service Company LLC, Indiana Crossroads Solar Generation LLC, and Meadow Lake Solar Park LLC.
	ER22–449–000	Northern Indiana Public Service Company LLC, Dunn's Bridge I Solar Generation LLC, and Dunns Bridge Solar Center, LLC.
E–11	ER20–1090–000; ER20–1961–000; ER20–1961–001.	NorthWestern Corporation. Southwest Power Pool, Inc.
E–12	EC21–56–000	Duke Energy Indiana, LLC, and GIC Infra Holdings Pte. Ltd.
E–13	EL21–79–000	*Illinois Municipal Electric Agency* v. *PJM Interconnection, L.L.C.*
E–14	EL21–90–000	*Basin Electric Power Cooperative and North Iowa Municipal Electric Cooperative Association* v. *Southwest Power Pool, Inc.*
E–15	EL21–47–001	*Green Development, LLC* v. *New England Power Company and Narragansett Electric Company.*
E–16	EL22–12–000	Persimmon Creek Wind Farm 1, LLC.
E–17	EL19–47–000	*Independent Market Monitor for PJM* v. *PJM Interconnection, L.L.C.*
	EL19–63–000	*Office of the People's Counsel for the District of Columbia, Delaware Division of the Public Advocate, Citizens Utility Board, Indiana Office of Utility Consumer Counselor, Maryland Office of People's Counsel, Pennsylvania Office of Consumer Advocate, West Virginia Consumer Advocate Division, and PJM Industrial Customer Coalition* v. *PJM Interconnection, L.L.C.*
	ER21–2444–000; ER21–2877–000	PJM Interconnection, L.L.C.
	Gas	
G–1	RM20–14–001	Five-Year Review of the Oil Pipeline Index.
G–2	RP21–1001–001; RP21–1001–000	Texas Eastern Transmission, LP.
	Hydro	
H–1	P–2883–009	Aquenergy Systems, LLC.
H–2	P–3023–014	Blackstone Hydro, Inc.
H–3	P–9985–033	Rivers Electric Company, Inc. and Rivers Electric LLC.
	Certificates	
C–1	IN19–4–000	Rover Pipeline, LLC and Energy Transfer Partners, L.P.
C–2	CP16–9–011; CP16–9–012	Algonguin Gas Transmission, LLC and Maritimes & Northeast Pipeline, L.L.C.
C–3	CP18–46–004	Adelphia Gateway, LLC.
C–4	CP15–490–002	Delfin LNG LLC.

The public is invited to listen to the meeting live at *http://ferc.capitolconnection.org/.* Anyone with internet access who desires to hear this event can do so by navigating to *www.ferc.gov*'s Calendar of Events and locating this event in the Calendar. The event will contain a link to its audio webcast. The Capitol Connection provides technical support for this free audio webcast. It will also offer access to this event via phone bridge for a fee. If you have any questions, visit *http://ferc.capitolconnection.org/* or contact Shirley Al-Jarani at 703–993–3104.

Issued: January 13, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–01040 Filed 1–14–22; 4:15 pm]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2701–061]

Erie Boulevard Hydropower, L.P.; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2701–061.

c. *Date filed:* February 26, 2021.

d. *Applicant:* Erie Boulevard Hydropower, L.P. (Erie).

e. *Name of Project:* West Canada Creek Hydroelectric Project (West Canada Creek Project).

f. *Location:* The existing project is located on West Canada Creek, a tributary of the Mohawk River, in the counties of Oneida and Herkimer, New York. The project does not occupy federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Steven Murphy, Director, Licensing, Brookfield Renewable, 33 West 1st Street South, Fulton, NY 13069, (315) 598–6130, *steven.murphy@brookfieldrenewable.com*.

i. *FERC Contact:* Emily Carter, (202) 502–6512 or *Emily.Carter@ferc.gov*.

j. *Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* 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, 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–2701–061.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The existing West Canada Creek Project consists of the following two developments:

The Prospect Development includes: (1) A 176-acre impoundment with a normal surface elevation of 1,161.5 feet; [1] (2) a dam that consists of a 306-foot-long, 45-foot-high concrete overflow spillway with three 27-foot-wide Tainter gates; (3) a 400-foot-long, 47-foot-high north dike and a 475-foot-long, 47-foot-high south dike; (4) a 4,500-foot-long, 22-foot-high canal extending from the south dike to a concrete intake; (5) a 430-foot-long, 13.5-foot-diameter steel penstock leading from the intake to the 76-foot-long, 62-foot-wide reinforced concrete powerhouse containing a single turbine generator unit with a nameplate capacity of 17.3 megawatts (MW); (6) an approximate 1.2-mile-long bypassed reach between the Prospect dam and the powerhouse; (7) 6.9-kilovolt (kV) generator leads that run from the powerhouse to a substation with a 15-kV breaker, 6.6/46-kV transformer, and a 46-kV switch connecting to the National Grid interconnection point within the substation; and (8) appurtenant facilities.

The Trenton Development includes: (1) A 288-foot-long and 60-foot-high concrete and masonry dam having an overflow section with a crest elevation of 1,017.9 feet, approximately 100 feet long surmounted by 6-foot hinged flashboards and a 10-foot by 15-foot sluice gate; (2) a concrete spillway approximately 160 feet long with a crest elevation of 1,016.2 feet surmounted by a pneumatic flashboard system with a crest elevation of 1,023.9 when fully inflated, discharging into a spillway channel excavated into rock around the east abutment of the dam; (3) a reservoir having a surface area of 9 acres and a gross storage capacity of 264 acre-feet at a normal pool elevation of 1,023.9 feet; (4) six 5-foot-diameter sluice pipes through the dam and two concrete-sealed 5-foot-diameter pipes; (5) a reinforced-concrete intake structure having a lift gate and trashracks along the west bank of the reservoir; (6) a 14-foot-diameter conduit comprising: (a) A 1,275-foot-long concrete-lined tunnel section; (b) a 40-foot-long steel-lined tunnel section; and (c) a 2,075-foot-long steel pipe section; (7) a bifurcation; (8) a steel penstock comprising: (a) A short 12-foot-diameter section connecting to a surge tank and leading to a 125-foot-long, 12-foot-diameter section connecting to a manifold; and (b) three 138-foot-long, 7-foot-diameter sections serving generating Units 5, 6, and 7; (9) a 263-foot-long, 7-foot-diameter steel penstock to Units 1 through 4; (10) Units 1 through 4 in Powerhouse No. 1 retired in-place and Powerhouse No. 2 containing generating Unit 5 (7.4 MW), Unit 6 (7.65 MW), and Unit 7 (7.4 MW)—for a total nameplate rating of 22.45–MW operated at a 255-foot head and a maximum flow of 1,450 cubic feet per second; (11) the 13.2-kV generator leads, the 15-kV switchgear, the 13.2/46-kV transformers, the 46-kV switchgear connecting to the main 46-kV bus, and the associated station services transformer banks and low voltage switchgear; and (12) appurtenant facilities.

The West Canada Creek Project operates off of outflows from the New York Power Authority's Hinckley-Jarvis Hydroelectric Project's (FERC No. 3211) reservoir (Hinckley Reservoir) that discharges into the upper end of the Prospect Development's reservoir.

Erie proposes to continue operating the project in the same manner as the current license and is not proposing to install any new structures as part of the relicensing. The project generated an annual average of 77,161 megawatt-hours between 2011 and 2019.

m. A copy of the application may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the

[1] All elevations refer to the National Geodetic Vertical Datum of 1929.

proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST,'' ''MOTION TO INTERVENE,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''PRELIMINARY TERMS AND CONDITIONS,'' or ''PRELIMINARY FISHWAY 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 protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. *Procedural Schedule:*

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions	March 2022.
Filing of Reply Comments	April 2022.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

q. A license applicant must file no later than 60 days following the date of issuance of the notice of acceptance and ready for environmental analysis provided for in § 5.22: (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.

Dated: January 12, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00922 Filed 1–18–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Privacy Act of 1974; System of Records

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Energy Regulatory Commission (FERC) is publishing notice of modifications to an existing FERC system of records, FERC–56 *titled Management, Administrative, and Payroll System (MAPS) Financials System,* and reissuing this system of records under its new name titled FERC–56–PeopleSoft Financials. In accordance with the Privacy Act of 1974, and to comply with the Office of Management and Budget (OMB) Memorandum M–17–12, *Preparing for and Responding to a Breach of Personally Identifiable Information,* January 3, 2017, this notice will create 13 new routine uses, including two new routine uses that will permit FERC to disclose information as necessary in response to an actual or suspected breach that pertains to a breach of its own records or to assist another agency in its efforts to respond to a breach. This System of Records Notice (SORN) also describes the Commission's financial management application name change, and the inclusion of new breach response routine uses.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice is effective upon publication, with the exception of the routine uses, which will go into effect February 18, 2022, unless comments have been received from interested members of the public requiring modification and republication of the notice. Please submit any comments by February 18, 2022.

ADDRESSES: Any person interested in commenting on the establishment of this modified system of records may do so by submitting comments electronically to: *Privacy@ferc.gov* (Include reference to ''PeopleSoft Financials—FERC–56'' in the subject line of the message.)

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Room 4A–05, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Mittal Desai, Chief Information Officer & Senior Agency Official for Privacy, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6432.

SUPPLEMENTARY INFORMATION: FERC maintains the PeopleSoft Financials system, the Commission's official financial management system that is used to account for and control appropriated resources and to maintain accounting and financial information associated with the operations of FERC. There are several changes to this System of Records Notice since its last publication.

First, the Management, Administrative, and Payroll System (MAPS) Financials System (FERC–56) System of Records Notice was last published in the **Federal Register** on September 23, 2009 (74 FR 48530). This notice is being modified to inform the public that this system has undergone a name change and will no longer be called Management, Administrative, and Payroll System Financials System. This system is now called PeopleSoft Financials. Second, FERC is modifying the existing routine uses for this system to include, among others, routine uses that allow FERC the ability to disclose records in response to a breach involving its own records or to assist another agency in its efforts to respond to a breach, in compliance with Office

of Management and Budget (OMB) Memorandum M–17–12.

SYSTEM NAME AND NUMBER:

PeopleSoft Financials—FERC–56

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE, Washington, DC 20426.

Third-Party Service Provider: Accenture Federal Services, 800 N Glebe Rd., #300, Arlington, VA 22203.

SYSTEM MANAGER(S):

System Manager/Project Manager, Federal Energy Regulatory Commission, Office of the Executive Director, Financial Information Technology and Travel Division, 888 First Street NE, Washington, DC 20426.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 31 U.S.C. 3511, *Prescribing accounting requirements and developing accounting systems.*

PURPOSE(S) OF THE SYSTEM:

The PeopleSoft Financials system is the official financial management system for FERC to account for and control appropriated resources and to maintain accounting and financial information associated with the normal operation of a U.S. government organization. The information in this system is used to make authorized payments for goods and services to companies or individuals doing business with FERC, to make authorized reimbursement payments to an employee, to prepare Internal Revenue Service (IRS) –1099 tax reports, and to account for regulatory fees owed to FERC. The system is also used to provide the Commission with advanced analytics and dashboard reports for financial, Human Resource (HR), and payroll data.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Peoplesoft Financials maintains records on salaried employees, non-salaried employees, current employees, former employees, vendors, consultants, legal representatives, representatives of regulated entities.

CATEGORIES OF RECORDS IN THE SYSTEM:

PeopleSoft Financials contains financial and Human Resources records on current and former employees, such as names, home addresses, bank account number, credit card numbers, invoices, claims for reimbursement, claims based on a legal settlement, Social Security Numbers (SSNs)/Taxpayer Identification Numbers (TINs), as well as HR actions (SF–50) and employee identifier. PeopleSoft Financials also contain financial records on vendors, consultants, legal representatives, as part of a contract or reimbursement claim, which include names, home or business addresses, vendor IDs, SSNs/TINs, bank account numbers for electronic fund transfer of payments, invoices, and claims for reimbursement.

RECORD SOURCE CATEGORIES:

Information is obtained from current and former employees seeking reimbursement from FERC for expenses incurred while on official travel or for training; current and former employees for the purposes of collecting receivables for FERC; current and former employees for the payment of legal settlements; current and former employees for the purposes of generating and maintaining payroll records and associated reporting on benefits and retirement data; and vendors and individual points of contact for a vendor seeking reimbursement for goods or services provided to FERC.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, information maintained in this system may be disclosed to authorized entities outside FERC for purposes determined to be relevant and necessary as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when: (1) FERC suspects or has confirmed that there has been a breach of the system of records; (2) FERC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To another Federal agency or Federal entity, when FERC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in: (1) Responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

3. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

4. To the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation.

5. To the Federal Labor Relations Authority or its General Counsel when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel.

6. To disclose information to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, where the record is relevant and necessary to the proceeding and the Government is a party to the judicial or administrative proceeding. In those cases where the Government is not a party to the proceeding, records may be disclosed if a subpoena has been signed by a judge.

7. To the Department of Justice (DOJ) for its use in providing legal advice to FERC or in representing FERC in a proceeding before a court, adjudicative body, or other administrative body, where the use of such information by the DOJ is deemed by FERC to be relevant and necessary to the advice or proceeding, and such proceeding names as a party in interest: (a) FERC; (b) Any employee of FERC in his or her official capacity; (c) Any employee of FERC in his or her individual capacity where DOJ has agreed to represent the employee; or (d) The United States, where FERC determines that litigation is likely to affect FERC or any of its components;

8. To non-Federal Personnel, such as Contractors, agents, or other authorized individuals performing work on a contract, service, cooperative agreement, job, or other activity on behalf of FERC or Federal Government and who have a need to access the information in the performance of their duties or activities;

9. To the National Archives and Records Administration in records management inspections and its role as Archivist, as permitted by 44 U.S.C. 2904 and 2906.

10. To appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, if the information may be relevant to a potential violation of civil or criminal law, rule, regulation, order.

11. To the Department of Treasury Users to issue authorized payments to companies and individuals or to issue authorized reimbursement payments to employees.

12. To IRS Users and companies or individuals who have received qualifying payments during the tax year as recipients of IRS–1099 reporting.

13. To disclose information to Government Services Administration (GSA), Department of the Interior, and other Federal Agencies under contractual obligations with FERC to assist in the management and transmittal of payroll and reimbursements.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic format, on a FedRAMP-authorized cloud service provider. In addition, all FERC employees and contractors with authorized access have undergone a thorough background security investigation. Data access is restricted to agency personnel or contractors whose responsibilities require access. Access to electronic records is controlled by ''User ID'' and password combination and/or other network access or security controls (*e.g.,* firewalls). Role based access is used to restrict electronic data access and the organization employs the principle of least privilege, allowing only authorized users with access (or processes acting on behalf of users) necessary to accomplish assigned tasks in accordance with organizational missions and business functions.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name of employee or name of vendor, and vendor ID (system unique) for both employees and vendors.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained in accordance with the applicable National Archives and Records Administration schedules, General Records Schedule (GRS) 5.2: Transitory and Intermediary Records (GRS 5.2 Item 020 Intermediary Records: *https://www.archives.gov/files/records-mgmt/grs/grs05-2.pdf*).'' Materials, including hard copy printouts derived from electronic records created on an ad hoc basis for reference purposes or to meet day-today business needs, are destroyed when the Commission determines that they are no longer needed for administrative, legal, audit, or other operational purposes. Additionally, PeopleSoft Financials system of records is retained as defined by the NARA approved Records Control Schedule, for financial records (*https://www.archives.gov/files/records-mgmt/grs/grs01-1.pdf*), and *https://www.archives.gov/files/records-mgmt/grs/grs02-2.pdf* for Human Resources records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Physical access to FERC is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All personnel are required to go through a background check prior to being granted access to the system. The system utilizes role-based access controls to restrict access to PII based on job function and role. Data-at-rest encryption is applied as a safeguard to all files containing PII Data. The system is secured with the safeguards required by FedRAMP and NIST SP 800–53.

RECORD ACCESS PROCEDURES:

Submit a Privacy Act Request

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended.

Privacy requests follow FERC's Freedom of Information Act (FOIA) request process. You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.*Written request for access to records should be directed to:

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

CONTESTING RECORD PROCEDURES:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended.

Privacy requests follow FERC's Freedom of Information Act (FOIA) request process. You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.*

Written request to contest records should be directed to:

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

NOTIFICATION PROCEDURES:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended.

Privacy requests follow FERC's Freedom of Information Act (FOIA) request process. You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.*

Written request for access to records should be directed to:

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Peoplesoft Financials was previously published in the **Federal Register** as Management, Administrative, and Payroll System (MAPS) Financials System. The previous **Federal Register** notice citation is **Federal Register** Vol.74, No. 183, Wednesday, September 23, 2009.

Issued: January 12, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00924 Filed 1–18–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–481–000.

Applicants: Williams Energy Resources LLC, Sequent Energy Management, LP.

Description: Joint Petition for Temporary Waiver of Capacity Release Regulations, et al. of Sequent Energy Management, LP, et al.

Filed Date: 1/11/22.

Accession Number: 20220111–5156.

Comment Date: 5 p.m. ET 1/24/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP20–980–004.

Applicants: East Tennessee Natural Gas, LLC.

Description: Refund Report: ETNG RP21–980 Refund Report to be effective N/A.

Filed Date: 1/12/22.

Accession Number: 20220112–5039.

Comment Date: 5 p.m. ET 1/24/22.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 12, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–00930 Filed 1–18–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3211–010]

Power Authority of New York; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 3211–010.

c. *Date filed:* July 31, 2020.

d. *Applicant:* Power Authority of the State of New York (Power Authority or NYPA).

e. *Name of Project:* Hinckley (Gregory B. Jarvis) Hydroelectric Project (Gregory B. Jarvis Project).

f. *Location:* The existing project is located on West Canada Creek, a tributary to the Mohawk River, at the Hinkley Reservoir dam, approximately 0.5 mile upstream of the Hamlet of Hinckley in the counties of Oneida and Herkimer, New York. The project does not affect federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Cindy Brady, New York Power Authority, 123 Main Street, White Plains, NY 10601; (914) 390–8070, *Cynthia.Brady@nypa.gov*.

i. *FERC Contact:* Emily Carter, (202) 502–6512, *emily.carter@ferc.gov*.

j. *Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* 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, 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–3211–010.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. *The existing Gregory B. Jarvis Project consists of the following facilities:* (1) A 570-foot-long dam; (2) a 2,600-foot-long south embankment dam; (3) a 400-foot-long ogee-type, cyclopean concrete spillway with a crest elevation of 1,225 feet;[1] (4) a 65-foot-long, 82-foot-high non-overflow cyclopean concrete intake structure with the top at 1,240 feet; (5) intake structure trash racks with 5.375-inch clear-spacing; (6) a 15-foot-diameter penstock, which bifurcates into two 90-foot-long, 10.5-foot-diameter penstocks; (7) two 3-foot by 4-foot gate valves that lead to a 42-inch-diameter sluice gate; (8) a 120-foot-long, 55-foot-wide, 43-foot-high semi-underground powerhouse located 200 feet downstream of the non-overflow intake structure; (9) two 4.5-megawatt horizontal Kaplan turbine-generator units; (10) an underground transformer; (11) a 280-foot-long tailrace; (12) a 60-inch-diameter water pipe used as a low-level outlet; (13) two 4.16-kilovolt (kV) generator leads routed 50 feet underground to an aboveground NYPA-owned 4.16-kV/46-kV step-up transformer; (14) an approximately 300-foot-long, 46-kV underground

[1] All elevations are referenced to the Hinckley Datum. Elevations referenced to the Hinckley Datum are 1.04 feet higher than elevations referenced to the National Geodetic Vertical Datum of 1929 [NGVD29 or mean sea level (msl)], thus, 1,225.0 feet Hinckley Datum corresponds to 1,223.96 feet NGVD29 or msl.

transmission line; and (15) appurtenant facilities.

The Gregory B. Jarvis Project takes advantage of the releases prescribed by the New York State Canal Corporation (NYS Canal Corp) in accordance with the 2012 Hinckley Reservoir Operating Diagram to generate power. Project operation is adjusted on a twice-weekly basis. NYPA does not deviate from the operating diagram unless directed to do so by the NYS Canal Corp. Reservoir levels are maintained between 1,195 feet and 1,225 feet (the elevation of the spillway crest); however, reservoir water levels can fall below 1,195 feet during a dry season. The Gregory B. Jarvis Project does not operate when reservoir levels are below 1,195 feet.

The project has two horizontal Kaplan units which are each capable of operating between 300 and 900 cubic feet per second (cfs) for a total hydraulic capacity of 1,800 cfs under normal operating conditions. At flows within the operating range of the units (300 to 1,800 cfs), the project provides outflow via generation. At flows below 300 cfs, or when the reservoir water surface elevation is below 1,195 feet, the project does not operate. During these conditions, the low-level sluice gate no. 4 is used to pass a minimum flow of 160 cfs. At flows greater than 1,800 cfs, and when the reservoir water surface elevation is greater than 1,225 feet, downstream releases are passed via a combination of generation and spillage.

NYPA occasionally operates the project in peaking mode. When NYPA is peaking, it will average the outflow required by the operating diagram over the course of the day. When operated in this manner, the project generates with a lower outflow during non-peak demand periods and then generates with a higher outflow during peak demand periods such that the total daily average flow is equal to the outflow prescribed by the operating diagram.

NYPA proposes to continue operating the project in the same manner as the current license and is not proposing to install any new structures as part of the relicensing. The project generated an annual average of approximately 28,863 megawatt-hours between 2010 and 2019.

m. A copy of the application is available for review on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST,'' ''MOTION TO INTERVENE,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''PRELIMINARY TERMS AND CONDITIONS,'' or ''PRELIMINARY FISHWAY 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 protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. *Procedural Schedule:* The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions	March 2022.
Filing of Reply Comments	April 2022.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

q. A license applicant must file no later than 60 days following the date of issuance of the notice of acceptance and ready for environmental analysis provided for in § 5.22: (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.

Dated: January 12, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00925 Filed 1–18–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–35–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on January 3, 2022, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 1300, Houston, TX 77002–2700 filed in the above referenced docket a prior notice pursuant to sections 157.205 and 157.216 of the Federal Energy Regulatory Commission's regulations

under the Natural Gas Act (NGA), requesting authorization to abandon four injection/withdrawal wells and associated pipelines and appurtenances, located in its Guernsey, Laurel, and McArthur Storage Fields in Guernsey, Hocking, and Vinton Counties, Ohio, respectively. Columbia proposes to abandon these facilities under authorities granted by its blanket certificate issued in Docket No. CP83–76–000.[1] The proposed abandonments will have no impact on Columbia's existing customers or affect Columbia's existing storage operations. The estimated cost for the Project is approximately $2.5 million, 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 David A. Alonzo, Manager, Project Authorizations, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, at (832) 320–5477 or *david_alonzo@tcenergy.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on March 14, 2022. 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,[3] any person [4] 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,[5] and must be submitted by the protest deadline, which is March 14, 2022. 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 [6] and the regulations under the NGA [7] by the intervention deadline for the project, which is March 14, 2022. 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 March 14, 2022. *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 CP22–35–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is

[1] *Columbia Gas Transmission Corporation* (predecessor to Columbia Gas Transmission, LLC), 22 FERC ¶ 62,029 (1983).

[2] 18 CFR (Code of Federal Regulations) 157.9.

[3] 18 CFR 157.205.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 157.205(e).

[6] 18 CFR 385.214.

[7] 18 CFR 157.10.

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 [8]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP22–35–000.

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: 700 Louisiana Street, Suite 1300, Houston, TX 77002–2700 or *david_alonzo@tcenergy.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: January 12, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–00923 Filed 1–18–22; 8:45 am]

BILLING CODE 6717–01–P

[8] 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

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–336–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 3864 Seven Cowboy Wind Project IGIA—Deficiency Response to be effective 10/15/2021.
Filed Date: 1/12/22.
Accession Number: 20220112–5062.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–487–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 3870 White Rock Wind West GIA—Deficiency Response to be effective 11/9/2021.
Filed Date: 1/12/22.
Accession Number: 20220112–5059.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–805–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2022–01–12_SA 3453 Ameren Illinois-Dressor Plains Solar 1st Rev GIA (J811) to be effective 12/28/2021.
Filed Date: 1/12/22.
Accession Number: 20220112–5056.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–806–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2022–01–12_SA 3366 Termination of Calhoun Solar-Consumers Energy FCA (J758) to be effective 1/13/2022.
Filed Date: 1/12/22.
Accession Number: 20220112–5058.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–807–000.
Applicants: CPV Keenan II Renewable Energy Company, LLC.
Description: § 205(d) Rate Filing: Category 1 Status Filing to be effective 3/14/2022.
Filed Date: 1/12/22.
Accession Number: 20220112–5066.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–808–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: Solarpack Develop.m.ent (Warrenton Solar) LGIA Filing to be effective 12/28/2021.
Filed Date: 1/12/22.
Accession Number: 20220112–5075.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–809–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 2987; Queue No. AC1–073 (amend) to be effective 4/4/2018.
Filed Date: 1/12/22.
Accession Number: 20220112–5092.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–810–000.
Applicants: Bicent (California) Malburg LLC.
Description: Tariff Amendment: Notice of Cancellation to be effective 1/13/2022.
Filed Date: 1/12/22.
Accession Number: 20220112–5096.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–811–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: Exelon NITSA (OR DA) SA 943 Rev 3 to be effective 1/1/2022.
Filed Date: 1/12/22.
Accession Number: 20220112–5098.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–812–000.
Applicants: ITC Midwest LLC.
Description: § 205(d) Rate Filing: Filing of Fifth Amended and Restated Corn Belt-IPL IA to be effective 3/14/2022.
Filed Date: 1/12/22.
Accession Number: 20220112–5110.
Comment Date: 5 p.m. ET 2/2/22.

Docket Numbers: ER22–813–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: NYISO Section 205 filing of LGIA among NYISO, LIPA and Peconic SA No. 2672 to be effective 12/31/2021.
Filed Date: 1/12/22.
Accession Number: 20220112–5115.
Comment Date: 5 p.m. ET 2/2/22.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's

Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 12, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–00929 Filed 1–18–22; 8:45 am]

BILLING CODE 6717–01–P

EXPORT-IMPORT BANK

[Public Notice: 2022–3001]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before February 18, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 11–05) or by email to Donna Schneider at *donna.schneider@exim.gov,* or by mail to Donna Schneider, Export-Import Bank, 811 Vermont Ave NW, Washington, DC 20571. The information collection tool can be reviewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib11-05.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Donna Schneider at *donna.schneider@exim.gov,* or 202–565–3612.

SUPPLEMENTARY INFORMATION: EXIM's borrowers, financial institution policy holders and guaranteed lenders provide this form to U.S. exporters, who certify to the eligibility of their exports for EXIM support. For direct loans and loan guarantees, the completed form is required to be submitted at time of disbursement and held by either the guaranteed lender or EXIM. For MT insurance, the completed forms are held by the financial institution, only to be submitted to EXIM in the event of a claim filing.

EXIM uses the referenced form to obtain information from exporters regarding the export transaction and content sourcing. These details are necessary to determine the value and legitimacy of EXIM financing support and claims submitted. It also provides the financial institutions a check on the export transaction's eligibility at the time it is fulfilling a financing request.

Title and Form Number: EIB 11–05 Exporter's Certificate for Loan Guarantee & MT Insurance Programs.

OMB Number: 3048–0043.

Type of Review: Regular.

Need and Use: The information collected will allow EXIM to determine compliance and content for transaction requests submitted to the Export-Import Bank under its insurance, guarantee, and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 2,000.

Estimated Time per Respondent: 30 minutes.

Annual Burden Hours: 1,000 hours.

Frequency of Reporting of Use: As required.

Government Expenses:

Reviewing Time per Year: 167 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $7,097.50 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $8,517.

Bassam Doughman,

IT Specialist.

[FR Doc. 2022–00949 Filed 1–18–22; 8:45 am]

BILLING CODE 6690–01–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Notice of Board Meeting

SUMMARY: Notice of the forthcoming regular meeting of the Board of Directors of the Farm Credit System Insurance Corporation (FCSIC), is hereby given in accordance with the provisions of Article VI of the Bylaws of the FCSIC.

Time and Date: 10:00 a.m., Thursday, January 27, 2022.

Place: Because of the COVID–19 pandemic, the public may only virtually attend the open portions of this meeting. If you would like to virtually attend, at least 24 hours in advance, visit *FCSIC.gov*, select ''News & Events,'' and then select ''Board Meetings.'' From there, access the linked ''Instructions for board meeting visitors.''

Status: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

Matters To be Considered:

Portions Open to the Public

- Approval of December 8, 2021 Minutes
- Review and Setting of Insurance Premium Rates
- Policy Statement—Insurance Premiums
- Policy Statement—Internal Controls, Audit Coverage & Committee Charter

Portions Closed to the Public

- Annual Report on Contracts
- Annual Report on Whistleblower Activity

For More Information Contact: If you need more information, need assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

Dated: January 12, 2022.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2022–00902 Filed 1–18–22; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0072]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Agency Information Collection Activities: Submission for OMB Review; Comment Request.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the request to renew the existing information collections described below (OMB Control No. 3064–0072).

DATES: Comments must be submitted on or before February 18, 2022.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency Website: https://www.fdic.gov/resources/regulations/federal-register-publications/index.html.*

• *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.

• *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

• *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

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: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: *Proposal to renew the following currently approved collections of information:*

1. *Title:* Acquisition Services Information Requirements.

OMB Number: 3064–0072.

Form Number: None.

Affected Public: Private sector, business and other for-profit entities.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN
[OMB No. 3064–0072]

	Type of burden	Obligation to respond	Number of respondents	Responses per respondent	Time per response	Frequency of response	Total annual estimated burden
Request for Proposal and Price Quotation (includes Basic Safeguards)—Solicitation/Award (Form 3700/55).	Reporting	Required to Obtain or Retain Benefits.	634	1	8.96	On Occasion	5,681
Request for Information	Reporting	Voluntary	107	1	58.74	On Occasion	6,285
Background Investigation Questionnaire for Contractor Personnel and Subcontractors (Form 1600/04).	Reporting	Required to Obtain or Retain Benefits.	185	1	0.33	On Occasion	61
Background Investigation Questionnaire for Contractors (Form 1600/07).	Reporting	Required to Obtain or Retain Benefits.	120	1	0.5	On Occasion	60
Background Investigation Questionnaire for Contractors (Form 1600/10).	Reporting	Required to Obtain or Retain Benefits.	185	1	0.17	On Occasion	31
Leasing Representations and Certifications (Form 3700/44).	Reporting	Required to Obtain or Retain Benefits.	15	1	1	On Occasion	15
Past Performance Questionnaire (Form 3700/57).	Reporting	Required to Obtain or Retain Benefits.	400	1	0.75	On Occasion	300
Contractor Representations and Certifications (Form 3700/04A).	Reporting	Required to Obtain or Retain Benefits.	1	1	0.67	On Occasion	1
Integrity and Fitness Representations and Certifications (Form 3700/12).	Reporting	Required to Obtain or Retain Benefits.	1	1	0.33	On Occasion	1
Prize Competitions—Application	Reporting	Required to Obtain or Retain Benefits.	100	1	1	On Occasion	100
Prize Competitions—Proposal	Reporting	Required to Obtain or Retain Benefits.	5	1	60	On Occasion	300
Innovation Pilot Programs—Application.	Reporting	Required to Obtain or Retain Benefits.	150	1	20	On Occasion	3,000
Innovation Pilot Programs—Proposal	Reporting	Required to Obtain or Retain Benefits.	90	1	60	On Occasion	5,400
Total Hourly Burden	.....	.....	.....	.....	.....	.....	21,235

General Description of Collection: This information collection involves the submission of various forms by (1) contractors who wish to do business with the FDIC or are currently under contract with the FDIC; (2) those vendors and parties participating in innovation pilot programs and prize competitions with the possibility of being awarded a contract; and (3) government agencies or commercial businesses that provide FDIC with past performance information. There is no change in the method or substance of the collection. However, the FDIC has amended this submission to account for the burdens associated with vendors and parties participating in innovation pilot programs and prize competitions.

The Federal Deposit Insurance Act (12 U.S.C. Section 1819) empowers the FDIC to enter into contracts using private sector contractors to provide goods or services. The Act also provides that the FDIC may promulgate policies and procedures to administer the powers granted to it, including the power to enter into contracts. Pursuant to such policies, the Acquisition and Corporate Services Branch of the FDIC's Division of Administration has developed forms and clauses to facilitate the procurement of goods and services from private sector contractors. The information collected through these forms and clauses fall under the definition of collection of information under the Paperwork Reduction Act of 1995 (PRA).

During the review of the renewal of this Acquisition Services Information Requirements information collection, FDIC determined that portions of the PRA burdens that are currently under the information collection entitled *Innovation Pilot Programs. (OMB No. 3064–0212)* should be transferred to this information collection (OMB No. 3064–0072). OMB No. 3064–0212 involves the collection of information from third parties (banks and firms in partnership with banks) who are invited to voluntarily propose time-limited pilot programs, which will be collected and considered by the FDIC on a case-by-case basis. FDIC has determined that the burdens associated with OMB No. 3064–0212 that contain the possibility of entering into a contract with the FDIC should be transferred to OMB No. 3064–0072. To avoid duplication of burden hours, OMB No. 3064–0212 will be separately amended to only contain the burden on IDIs and third parties that are involved in the various projects that third parties may engage in. FDIC determined that OMB No. 3064–0072 should include the burden involved with the preparation and submission of applications to participate in FDIC-sponsored or co-sponsored prize competitions if the outcome of those prize competitions includes the possibility of entering into a contract with the FDIC. These burdens are similar to the burdens currently under the IC entitled *Generic Clearance for Prize Competition Participation* (OMB No. 3064–0211). However, OMB No. 3064–0211 contains and will continue to contain those burdens associated with prize competitions whose outcomes do not include the possibility of a entering into a contract with the FDIC.

New Burden: Prize Competitions—Estimated Number of Respondents, Responses and Hourly Burdens

As described above, this ICR adds to OMB No. 3064–0072 the burdens involved with the preparation and submission of applications to participate in FDIC-sponsored or co-sponsored prize competitions if the outcomes of those prize competitions include the possibility of entering into a contract with the FDIC. The information associated with this burden are collected from potential and actual participants (including technologists, coders, engineers and developers; consumers of financial services; consumer advocates; academics; members of trade groups and other associations; individuals connected to financial institutions, community banks, and financial and bank service and technology providers; software, data, and technology firms; and other members of the public) of those prize competitions. The FDIC collects information from respondents during both an application phase and during a proposal phase.

1. *Application Phase:* The FDIC has never conducted a prize competition where outcomes included the possibility of entering into a contract with the FDIC. FDIC anticipates that approximately 100 applications would be received if the FDIC were to initiate such a prize competition. For the purposes of this ICR, FDIC assumes that each application is submitted by a distinct respondent. Thus, in the above burden table, for the line item Prize Competition—Application, FDIC assumes that the number of responses per respondent is one and use a respondent count of 100 per year.

In order for the FDIC to determine which applicants will be eligible and selected to participate in FDIC prize competitions, the FDIC will request that potential participants provide their name, contact information, address, and such other information that may be necessary to evaluate applicants' qualifications and ability to participate in the event as well as to match the applicants' anticipated role to the needs of the competition. Applicants will also be asked to acknowledge the terms and conditions of participating in the prize competition. Based on their experience with previous prize competitions, FDIC estimates that respondents will spend, on average, one hour to prepare and submit an application.

2. *Proposal Phase:* Certain participants in these prize competitions may be invited to present a contract proposal to be considered by the FDIC. Should such a prize competition occur, FDIC assumes that it would receive five contract proposals per year. For the purposes of this ICR, FDIC assumes that each proposal is submitted by a distinct respondent. Thus, for the line item Prize Competition—Proposal, FDIC assumes that the number of responses per respondent is one and use a respondent count of five per year.

Based on experience with previous prize competitions, FDIC expects that respondents will spend, on average, 60 hours to prepare and submit a proposal. Thus, for the line item Prize Competition—Proposal, FDIC estimates a time burden of 60 hours per response.

Transferred Burden From OMB No. 3064–0212: Innovation Pilot Program—Estimated Number of Respondents, Responses and Hourly Burdens

As described above, this ICR transfers the burdens that contain the possibility of entering into a contract with the FDIC from OMB No. 3064–0212 to OMB No. 3064–0072. The information associated with this burden are collected from innovators who are invited to voluntarily propose time-limited pilot programs. The program is typically conducted in four phases, with a declining number of companies advancing at each phase. The FDIC provides fixed monetary awards for the successful completion of some of these phases. In order to evaluate potential contractors, the FDIC collects information from respondents twice: During an application phase and during a proposal phase.

1. Application Phase: The FDIC issues a call for concept papers as a general solicitation. Interested parties respond by submitting concept papers, thus becoming offerors. The FDIC then subjectively assesses those papers to determine its confidence in the prospective merits of those concept papers as well as the FDIC's confidence in the offeror's apparent ability to transform concepts into real-world solutions. FDIC used its experience with the first Innovation Pilot Program [1] to estimate that 50 concept papers are submitted to the FDIC in response to a call. Although one company could submit multiple concept papers to one call, or different concept papers to different calls, the FDIC considers a concept paper submission for each call to be from a distinct respondent. The FDIC anticipates issuing three calls per year. Thus, for purposes of this information collection item, FDIC estimates 150 respondents per year and one response per respondent per year. FDIC believes that the hourly burden for preparing concept papers to be similar to that of RFPs. However, the applications for pilot programs are usually more extensive than the average RFP. Based on the hourly burden estimated for RFPs, FDIC estimates that each application will take 20 hours to

[1] The first Innovation Pilot Program, Rapid Phased Prototyping (RPP), began in August 2020. Details for RPP can be found at *https://www.fdic.gov/fditech/rpp.html* (last accessed September 30, 2021). The proposal submission phase for RPP is expected to finish in 2021. The FDIC received 35 applications for RPP; FDIC conservatively estimates 50 responses per pilot program to account for the fact that future collections could receive increased interest. The FDIC also anticipates holding up to three pilots a year, for a total of 150 estimated applications per year.

prepare and submit. Thus, for the line item Innovation Pilot Program—Application, FDIC estimates a time burden of 20 hours per response.

2. Proposal Phase: During a pilot program, all contractors who are participating will provide an initial summary of the terms and conditions (including price, deliverables, intellectual property rights, and so forth) it contemplates proposing for a follow-on pilot. The FDIC may provide feedback to the contractor and contractors may resubmit their proposal one or more times based on feedback received. Based on their experience with rapid Phase Prototyping (RPP), FDIC estimates that approximately 60 percent of applications received in response to calls for concept papers, or 90 applications per year,[2] will be invited to submit contract proposal. As above, the FDIC assumes each response to be from a distinct respondent. Thus, for the line item Innovation Pilot Program—Proposal, FDIC estimates 90 respondents per year and one response per respondent per year. FDIC believes that, given the iterative nature of the RPP process, it is likely that contractors will go through multiple iterations of contract proposals. FDIC assumes that each respondent will have to revise their submission twice, on average. In addition, these contract proposals include pricing, terms, and conditions, which will require more time than the concept papers. Given these differences, FDIC estimates that each response to an Innovation Pilot Program—Proposal will take 60 hours to prepare and submit.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

[2] 90 contract proposals = 50 application per call * 3 calls per year * 60%.

Dated at Washington, DC, this 12th day of January 2022.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–00865 Filed 1–18–22; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

[Notice 2022–01]

Filing Dates for the California Special Elections in the 22nd Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: California has scheduled a Special General Election on April 5, 2022, to fill the U.S. House of Representatives seat in the 22nd Congressional District vacated by Representative Devin Nunes. Under California law, a majority winner in a special election is declared elected. Should no candidate achieve a majority vote, a Special Runoff Election will be held on June 7, 2022, between the top two vote-getters. Political committees participating in the California special elections are required to file pre- and post-election reports. Filing deadlines for these reports are affected by whether one or two elections are held.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, 1050 First Street NE, Washington, DC 20463; Telephone: (202) 694–1100; Toll Free (800) 424–9530.

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

All principal campaign committees of candidates who participate in the California Special General and Special Runoff Elections shall file a 12-day Pre-General Report on March 24, 2022; a 12-day Pre-Runoff Report on May 26, 2022; and a 30-day Post-Runoff Report on July 7, 2022. (See charts below for the closing date for each report.)

If both elections are held, all principal campaign committees of candidates who participate only in the California Special General Election shall file a 12-day Pre-General Report on March 24, 2022. (See charts below for the closing date for each report.)

If only one election is held, all principal campaign committees of candidates in the Special General Election shall file a 12-day Pre-General Report on March 24, 2022; and a 30-day Post-General Report on May 5, 2022. (See charts below for the closing date for each report.)

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See charts below for the closing date for each report).

Unauthorized Committees (PACs and Party Committees)

Political committees not filing monthly are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the California Special General and/or Special Runoff Elections by the close of books for the applicable report(s). (See charts below for the closing date for each report.)

Committees filing monthly that make contributions or expenditures in connection with the California Special General or Special Runoff Elections will continue to file according to the monthly reporting schedule.

Additional disclosure information for the California special elections may be found on the FEC website at *https://www.fec.gov/help-candidates-and-committees/dates-and-deadlines/.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and leadership PACs that are otherwise required to file reports in connection with the special elections must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of the lobbyist bundling threshold during the special election reporting periods. (See charts below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b), 110.17(e)(2), (f).

The lobbyist bundling disclosure threshold for calendar year 2021 was $19,300. This threshold amount may change in 2022 based upon the annual cost of living adjustment (COLA). As soon as the adjusted threshold amount is available, the Commission will publish it in the **Federal Register** and post it on its website. 11 CFR 104.22(g) and 110.17(e)(2).

CALENDAR OF REPORTING DATES FOR CALIFORNIA SPECIAL ELECTIONS

Report	Close of books [1]	Reg./cert. & overnight mailing deadline	Filing deadline
If *Only* the Special General (04/05/2022) Is Held, Committees Involved Must File			
Pre-General	03/16/2022	03/21/2022	03/24/2022
April Quarterly	03/31/2022	04/15/2022	04/15/2022
Post-General	04/25/2022	05/05/2022	05/05/2022
July Quarterly	06/30/2022	07/15/2022	07/15/2022
If Two Elections Are Held, Committees Involved in *Only* the Special General (04/05/2022) Must File			
Pre-General	03/16/2022	03/21/2022	03/24/2022
April Quarterly	03/31/2022	04/15/2022	04/15/2022
Committees Involved in Both the Special General (04/05/2022) and Special Runoff (06/07/2022) Must File			
Pre-General	03/16/2022	03/21/2022	03/24/2022
April Quarterly	03/31/2022	04/15/2022	04/15/2022
Pre-Runoff	05/18/2022	05/23/2022	05/26/2022
Post-Runoff	06/27/2022	07/07/2022	07/07/2022
July Quarterly	—- WAIVED —-		
October Quarterly	09/30/2022	10/15/2022	[2] 10/15/2022
Committees Involved In *Only* the Special Runoff (06/07/2022) Must File			
Pre-Runoff	05/18/2022	05/23/2022	05/26/2022
Post-Runoff	06/27/2022	07/07/2022	07/07/2022
July Quarterly	— WAIVED —		
October Quarterly	09/30/2022	10/15/2022	[2] 10/15/2022

[1] The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.

[2] Notice that this filing deadline falls on a weekend or federal holiday. Filing deadlines are not extended when they fall on nonworking days. Accordingly, reports filed by methods other than registered, certified or overnight mail, or electronically, must be received before the Commission's close of business on the last business day before the deadline.

Dated: January 12, 2022.

On behalf of the Commission.

Allen J. Dickerson,

Chairman, Federal Election Commission.

[FR Doc. 2022–00945 Filed 1–18–22; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL TRADE COMMISSION

[File No. 172 3196]

Dun & Bradstreet, Inc.; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 18, 2022.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''Dun & Bradstreet, Inc.; File No. 172 3196'' on your comment and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Dana C. Barragate, Attorney (216–263–3402), Federal Trade Commission, East Central Region, 1111 Superior Avenue, Suite 200, Cleveland, OH 44114–2507.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 18, 2022. Write ''Dun & Bradstreet, Inc.; File No. 172 3196'' on your comment. Your comment—

including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Dun & Bradstreet, Inc.; File No. 172 3196'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. Your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 18, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a proposed consent order (''Proposed Order'') from Dun & Bradstreet, Inc. (''D&B''). The Proposed Order has been placed on the public record for 30 days to receive comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's Proposed Order.

This matter involves D&B's sale of paid CreditBuilder and related products (''CreditBuilder products''). D&B typically marketed CreditBuilder products to small and mid-sized businesses (who are the consumers in this matter) as a means to improve what D&B reports about the business on its commercial credit reports. The FTC's proposed five-count complaint challenges several of D&B's CreditBuilder sales and renewal practices as deceptive, and also alleges that certain conduct was unfair, all in violation of Section 5(a) of the Federal Trade Commission Act (''FTC Act''), 15 U.S.C. 45(a).

The first four counts of the proposed complaint allege deceptive acts or practices in violation of the FTC Act.

- *First,* the complaint alleges D&B's representations that a business could use CreditBuilder products to have previously unreported commercial payment experiences added to its credit report, and that D&B would actively assist CreditBuilder customers in adding payment experiences, were deceptive because, in numerous instances, customers did not get payment experiences added, and D&B did not actively assist the customer in adding payment experiences.
- *Second,* the complaint alleges D&B made false claims that CreditBuilder products were required for D&B to conduct a background check on the business or to complete its D&B report, including providing the business with a full set of scores and ratings.
- *Third,* the complaint alleges that, in connection with collecting updated payment information for CreditBuilder products scheduled to renew, D&B sometimes misrepresented that D&B was collecting payment for and renewing the product that the business purchased the prior term, when, in fact, D&B was collecting payment information to enroll the customer in a different product from the one to which the customer previously subscribed.
- *Fourth,* the complaint alleges that when D&B collected customer credit card information for payment, it failed to adequately disclose practices that resulted in recurring and increasing charges, including automatic billing.

In addition to the alleged deceptive marketing and renewal practices, the complaint alleges in its *fifth* count that D&B engaged in an unfair practice by reporting incorrect information on businesses' credit reports while failing to provide those businesses with a reasonable means to dispute such information and have inaccurate information corrected. The proposed complaint alleges this conduct caused or is likely to cause substantial injury to consumers that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoided by consumers themselves. Such practice constitutes an unfair act or practice in violation of Section 5 of the FTC Act.

The Proposed Order is designed to prevent D&B from engaging in similar acts or practices in the future. It includes injunctive relief to address these alleged violations.

- Part I prohibits future deceptive acts and practices similar to those at issue in the complaint by prohibiting D&B from misrepresenting:

○ That using D&B's product is likely to allow a business to have its previously unreported commercial payment experiences added to its credit report;

○ That D&B will actively assist a business in adding its unreported commercial payment experiences to its credit report;

○ That using D&B's product is likely to help a business build or improve its credit report;

○ The ease with which information or payment experiences can be added to a business's credit report; and

○ That D&B's product is needed when it is not, and that a product will enable a prospective customer to have a ''complete'' file.

• Part I also features ancillary relief relating to the challenged conduct by prohibiting misrepresentations relating to what payment experiences customers can add, as well as to D&B's renewal and charging practices.

• Part II provides additional specific relief relating to D&B's renewal and charging practices for products covered under the Proposed Order, to make sure that D&B makes clear disclosures about renewals both before a customer subscribes and during the period of the subscription.

• Parts III and IV require D&B to make certain disclosures to potential customers of CreditBuilder products, so that those potential customers can make better informed decisions about whether to purchase the products.

• Part V sets out specific requirements for D&B to follow when a business disputes information that D&B reports about it. The requirements of this Part V apply generally and are not limited only to D&B customers.

• Part VI requires D&B to offer refunds (or partial refunds) to certain customers and former customers of CreditBuilder products. Refund or partial refund eligibility under the Proposed Order will depend on customers' specific circumstances and how they used or attempted to use their CreditBuilder products.

• Part VII requires D&B to send notices to all current customers of paid products covered under the Proposed Order that automatically renew.

Parts VIII through XII are reporting and compliance provisions. Part VIII mandates that D&B acknowledge receipt of the Proposed Order and, for three years, distribute the Proposed Order to certain employees and agents and secure acknowledgments from recipients of the Proposed Order. Part IX requires D&B to submit compliance reports to the FTC one year after the order's issuance and submit additional reports when certain events occur. Part X requires that, for 10 years, D&B creates certain records and retain them for at least 5 years. Part XI provides for the FTC's continued compliance monitoring of D&B's activity during the Proposed Order's effective dates. Part XII is a provision ''sunsetting'' the Proposed Order after 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the Proposed Order. It is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify in any way the Proposed Order's terms.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2022–00938 Filed 1–18–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment for the Theator, Inc. PSO

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ accepted a notification of proposed voluntary relinquishment from the Theator, Inc. PSO, PSO number P0218, of its status as a PSO, and has delisted the PSO accordingly.

DATES: The delisting was effective at 12:00 Midnight ET (2400) on December 22, 2021.

ADDRESSES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, 42 U.S.C. 299b–21 to 299b–26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the Theator, Inc. PSO to voluntarily relinquish its status as a PSO. Accordingly, the Theator, Inc. PSO, P0218, was delisted effective at 12:00 Midnight ET (2400) on December 22, 2021.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

Dated: January 12, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–00906 Filed 1–18–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DP22–001, Real-World Effectiveness of Structured Lifestyle Interventions in Preventing Type 2 Diabetes.

Date: March 23, 2022.

Time: 10:30 a.m.–6:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Jaya Raman Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–8, Atlanta, Georgia 30341–3717, Telephone: (770) 488–6511; Email: *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–00868 Filed 1–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DP22–002, Epidemiology of Lupus: Longitudinal Studies in Population-Based Cohorts.

Date: March 17, 2022.

Time: 11:00 a.m.–6:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Jaya Raman, Ph.D., Scientific Review Officer, National Center for Chronic Disease and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–8, Atlanta, Georgia 30341–3717, Telephone: (770) 488–6511, Email: *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–00867 Filed 1–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2022–0003]

Draft Policy Statement for Biosafety Level 4 (BSL–4) and Animal BSL–4 (ABSL–4) Laboratory Verification; Notice of Availability

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comment on a draft policy statement regarding Biosafety Level 4 (BSL–4)/Animal Biosafety Level 4 (ABSL–4) verification requirements. The policy statement, once finalized, will assist individuals and entities in verifying that the facility design parameters and operational procedures, including heating, ventilation, and air conditioning (HVAC) systems, in BSL–4 and/or ABLS–4 laboratories are functioning as intended to meet the biosafety sufficiency requirement in the HHS/CDC select agent regulations.

DATES: Submit written or electronic comments by March 21, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0003, by either of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329.

Instructions: All submissions received must include the Agency name and Docket No. CDC–2022–0003. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. *Do not send comments by email. CDC does not accept comments by email.*

Docket Access: For access to the docket to read background documents or comments received, or to download

an electronic version of the draft policy statement, go to *http://www.regulations.gov.* Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION:

A. Legal Authority

HHS/CDC is issuing this draft policy under the authority of sections 201–204 and 221 of Title II of Public Law 107–188, (42 U.S.C. 262a).

B. Background

For entities that possess select agents and toxins, the HHS select agent and toxin regulations (42 CFR part 73) require that ''biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.,* physical structure and features of the entity, and operational and procedural safeguards)'' (42 CFR 73.12(b)). BSL–4 and ABSL–4 laboratory facility specifications and operational procedures are used for work with dangerous and exotic biological agents that could easily be aerosol transmitted within the laboratory, cause severe to fatal disease in humans, and typically do not have available vaccines or treatments. Therefore, these laboratories must implement and maintain the highest level of biosafety precautions for containment.

HHS/CDC reviews how entities that maintain BSL–4 and/or ABSL–4 laboratories have verified that the design and operational parameters, including HVAC, are functioning properly when determining if entities have met the sufficiency requirement in section 12(b) of the HHS select agent and toxin regulations. In developing a biosafety plan, an individual or entity should consider requirements found in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (42 CFR 73.12(c)). HHS/CDC has developed a draft policy statement for BSL–4 and ABSL–4 laboratory verification based on the standards found in the 6th edition of the BMBL:

- *BSL–4 D16(a):* The ventilation system is designed to maintain the laboratory at negative pressure to surrounding areas and to provide differential pressure or directional airflow as appropriate between adjacent areas within the laboratory.
- *ABSL–4 D16(a):* The supply and exhaust components of the ventilation system are designed to maintain the ABSL–4 facility at negative pressure to surrounding areas and to provide differential pressure or directional airflow as appropriate between adjacent areas within the facility.
- *BSL–4 D20:* The facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.
- *ABSL–4 D21:* The ABSL–4 facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.

HHS/CDC is requesting public comment on a draft policy statement on BSL–4/ABSL–4 laboratory verifications standards, including HVAC, to aid individuals and entities in verifying that these laboratories are properly functioning. We are making this policy document available to the public in the Supplementary Materials tab of the docket at *www.regulations.gov* for review and comment. All comments, such as items related to the appropriate acceptance criteria used to ensure systems are functioning as intended and documentation to demonstrate the sufficiency requirement has been met, that we receive on or before March 21, 2022 will be carefully reviewed and considered.

Dated: January 13, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–00928 Filed 1–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–1255]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Emergency Cruise Ship Outbreak Investigations (CSOIs)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on 10/13/2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of

Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Emergency Cruise Ship Outbreak Investigations (CSOIs) (OMB Control No. 0920–1255, Exp. 03/30/2022)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Established in 1975 as a cooperative activity with the cruise ship industry, the Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program (VSP) develops and implements comprehensive sanitation programs to minimize the risk of gastrointestinal diseases, by coordinating and conducting operational inspections, ongoing surveillance of gastrointestinal illness, and outbreak investigations on vessels.

Under the authority of the Public Health Service Act (42 U.S.C. Sections 264 and 269), the VSP is requesting a three-year Paperwork Reduction Act (PRA) clearance for a revision of an existing generic clearance information collection request (Generic ICR), titled ''Emergency Cruise Ship Outbreak Investigations (CSOIs)'' (OMB Control Number 0020–1255, expiration date 03/30/2022). This Generic ICR provides the quick turn-around necessary to conduct emergency CSOIs in response to acute gastroenteritis (AGE) outbreaks. CSOIs are used to determine the causative agents and their sources, modes of transmission, or risk factors. The VSP's jurisdiction includes passenger vessels carrying 13 or more people sailing from foreign ports and within 15 days of arriving at a U.S. port.

VSP uses its syndromic surveillance system called the ''Maritime Illness and Death Reporting System (MIDRS)'' (OMB Control No. 0920–1260, expiration date 04/30/2022) to collect aggregate data about the number of people onboard ships in VSP's jurisdiction who are experiencing AGE symptoms. When the levels of illness meet VSP's alert threshold (*i.e.,* at least 2% in either the passenger or crew populations), a special report is made to VSP via MIDRS, and remote environmental health and epidemiologic assistance is provided.

VSP considers an outbreak to be greater than or equal to 3% of reportable AGE cases in either guest or crew populations. When outbreaks occur, cruise ships submit daily reports of cases in the form of AGE logs to VSP. When assistance is needed due to AGE outbreaks on cruise ships, this often requires VSP to deploy a response team to meet the ship in port within 24 hours of reaching the outbreak threshold, and in some cases deploying the response team to board the ship before its U.S. arrival and sail back to the U.S. port of disembarkation to conduct a more detailed and comprehensive epidemiologic and environmental health evaluation of the outbreak.

Causative agent, sources of exposure, modes of transmission, and risk factors can be ascertained by gathering the following types of information from both the affected and (seemingly) unaffected populations:

- Demographic information,
- Pre-embarkation travel information,
- Symptoms, including type, onset, duration,
- Contact with people who were sick or their body fluids,
- Participation in ship and shore activities,
- Locations of eating and drinking, and
- Foods and beverages consumed both on the ship and on shore.

Rapid and flexible data collection is imperative given the mobile environment, the remaining duration of the voyage left for investigation, and the loss to follow-up if delays allow passengers to disembark and leave the ship, including those returning to locations outside of the U.S.

This Generic ICR will cover investigations that meet all of the following criteria:

- The investigation is urgent in nature (*i.e.,* timely data are needed to inform rapid public health action to prevent or reduce morbidity or mortality).
- The investigation is characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors.
- One or more CDC staff (including trainees and fellows) will be deployed to the field.
- Most CSOIs involve 2 to 5 days of data collection; data collection is completed in 30 days or less.

This Generic ICR excludes each of the following:

- Investigations related to non-urgent outbreaks or events.
- Investigations conducted for the primary purpose of program evaluation, needs assessment, or research (*e.g.,* to contribute to generalizable knowledge).
- Investigations with data collection expected for greater than 30 days.

The cruise ship industry experience in 2020 and 2021 was largely not considered in this revision due to the disruption caused by the COVID–19 pandemic. Since the first quarter of 2020, the COVID–19 pandemic disrupted the number of cruise ship voyages operating to U.S. ports of call. Between March 2020 and October 2021, cruise industry operations were suspended under a federally issued No Sail Order, and then subsequently under a Conditional Sailing Order to prevent the risk of introducing, transmitting, and spreading COVID–19 by cruise ship travelers. The VSP conducted the following number of remote environmental health and epidemiologic consultations for outbreaks, greater than or equal to 3% of reportable AGE cases, by reviewing existing MIDRS records: 10 in 2019, none in 2020, and one in 2021. No new information was collected. Additionally, the VSP conducted no CSOIs in the past three years.

Under the most recent MIDRS revision, cruise ships report an estimated 3,370 AGE cases (575 crew and 2,795 passenger) per voyage; therefore, VSP uses this same increase of 870 over the previously approved 2,500 AGE cases per voyage for each CSOI. Previously, respondents were counted as either taking the self-administered questionnaire or the interview. Currently, all AGE cases are requested to complete a self-administered questionnaire. Then a 15% subset of these AGE cases may be interviewed for additional information about their illness. Furthermore, a 40% subset of AGE cases may be asked for biospecimens for laboratory confirmation of the causative agent. The VSP uses existing laboratory biospecimen collection forms approved under other CDC ICRs (OMB Control No. 0920–0004, exp. date 10/31/2020; OMB Control No. 0920–1309, exp. date 11/30/2023).

As previously approved, up to 10 CSOIs may be conducted annually in response to cruise ship AGE outbreaks. This results in a revised total of 52,234 responses for 10 CSOIs per year; this is an increase of 27,232 responses over the previously approved 25,000. The total annualized time burden has increased to 13,060 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Cruise ship crew	Self-administered Questionnaire	5,750	1	15/60
	Interview	862	1	15/60
	Biospecimen Collection	2,300	1	15/60
Cruise ship passengers	Self-administered Questionnaire	27,950	1	15/60
	Interview	4,192	1	15/60
	Biospecimen Collection	11,180	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–00856 Filed 1–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0607]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''The National Violent Death Reporting System (NVDRS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 6, 2021, to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The National Violent Death Reporting System (NVDRS) (OMB Control No. 0920–0607, Exp. 7/31/2023)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Violence is a public health problem. The World Health Organization has estimated that 804,000 suicides and 475,000 homicides occurred in the year 2012 worldwide. Violence in the United States is a particular problem for the young; suicide and homicide were among the top four leading causes of death for Americans 10–34 and 1–34 years of age in 2015, respectively. In 2002 Congress approved the first appropriation to start the National Violent Death Reporting System (NVDRS). NVDRS is coordinated and funded at the federal level but is dependent on separate data collection efforts managed by the state health department (or their bona fide agent) in each state.

NVDRS, implemented by the Centers for Disease Control and Prevention (CDC), is a state-based surveillance system developed to monitor the occurrence of violent deaths (*i.e.,* homicide, suicide, undetermined deaths, and unintentional firearm deaths) in the United States (U.S.) by collecting comprehensive, detailed, useful, and timely data from multiple sources (*e.g.,* death certificates, coroner/medical examiner reports, law enforcement reports) into a useable, anonymous database. NVDRS is an ongoing surveillance system that captures annual violent death counts and circumstances that precipitate each violent incident. Violent deaths are defined as any death resulting from the intentional use of physical force or power (*e.g.,* threats or intimidation) against oneself, another person, or against a group or community. CDC aggregates de-identified data from each state into one large national database that is analyzed and released in annual reports and publications. Descriptive analyses such as frequencies and rates are employed. A restricted access database is available for researchers to request access to NVDRS data for analysis and a web-based query system is open for public use that allows for electronic querying of data. NVDRS generates public health surveillance information at the national, state, and local levels that is more detailed, useful, and timely. Government, state and local communities have used NVDRS data to develop and evaluate prevention programs and strategies. NVDRS is also used to understand magnitude, trends, and characteristics of violent death and what factors protect people or put them at risk for experiencing violence.

CDC has received OMB approval for NVDRS since 2004. In this revision request CDC describes plans to (1) implement updates to the web-based system to improve performance, functionality, and accessibility, (2) add

13 new data elements to the web-based system, (3) add a School Associated Violent Death (SAVD) module as part of the NVDRS web-based system, (4) add new variables to NVDRS software, and (5) add a Public Safety Officer suicide module as part of the NVDRS web-based system.

In 2018, the NVDRS expanded by adding 10 new states and now includes all 50 states, the District of Columbia, and U.S. territory health departments (56 jurisdictions). Jurisdictions are funded to abstract standard data elements from three primary data sources: Death certificates, coroner/medical examiner records, and law enforcement records, into a web-based data entry system, supplied by CDC. The exception is for large states that have more than 2,000 violent deaths occurring per year; these states have the option to collect data in selected counties/targeted areas that represent at least 40% of all violent deaths occurring within their jurisdiction, and some may achieve statewide coverage. The goal of NVDRS is to collect state-wide data in all funded entities. No sampling methods will be employed.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 41,827.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Agencies	Web-based Data Entry	56	1,350	30/60
	School Associated Violent Death Module	45	1	30/60
	Public Safety Officer Suicide Reporting Module	56	429	10/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–00855 Filed 1–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #17]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance [1] related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: The necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 2, 2022.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 (#77), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may access CMS' website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* CHIP State Plan Eligibility; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* This revision relates to the American Rescue Plan Act of 2021 and the new extended postpartum coverage option available to Medicaid and CHIP for a 5 year period beginning April 1, 2022 through March 31, 2027. If a state elects this option in Medicaid, it is required to also provide extended postpartum coverage in its separate

[1] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRA_Gen_ICRs_5-28-2010.pdf.*

CHIP. We are revising an existing CHIP template, the CS27, to capture this new requirement. We are also revising the portion of the template regarding optional continuous eligibility for children to align with finalized continuous eligibility regulations at 42 CFR 457.342. *Form Number:* CMS–10398 (#17) (OMB control number: 0938–1148); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 2,800. (For policy questions regarding this collection contact: Kristin Edwards at 410–786–5480.)

Dated: January 13, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–00937 Filed 1–18–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Child Support Annual Data Report (OCSE–157) (OMB No.: 0970–0177)

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), is requesting approval of a 3-year extension of the Child Support Annual Data Report and Instructions (OCSE–157). The current Office of Management and Budget (OMB) approval expires on March 31, 2022. OCSE made minor revisions to the form's instructions.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Each year, states are required to provide OCSE with their child support information pertaining to case inventory, performance status, and accomplishments in the following areas: Paternity establishment, services requested and provided, medical support, collections due and distributed, staff, program expenditures, non-cooperation and good cause, and administrative enforcement. The information collected from the Child Support Annual Data Report (OCSE–157) enables OCSE to (1) report child support enforcement activities to Congress as required by law, (2) calculate states' incentive measures for performance and assess performance indicators utilized in the program, and (3) assist OCSE in monitoring and evaluating state child support programs.

Respondents: State and Local Child Support Agencies.

ANNUAL BURDEN ESTIMATES

Collection instrument	Total number of annual respondents	Total number of annual responses per respondent	Average annual burden hour per response	Annual burden hours
OCSE–157 Report and Instructions	54	1	7	378

Estimated Total Annual Burden Hours: 378.

Authority: 42 U.S.C. 652(a) and (g), and 669.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–00917 Filed 1–18–22; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Centers for Independent Living Program Performance Report (CIL PPR) (0985–0061)

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to Centers for Independent Living Program Performance Report (CIL PPR) (0985–0061).

DATES: Comments on the information collection request must be submitted electronically by 11:59 p.m. (EST) or postmarked by February 18, 2022.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office

Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795–7606 or *OILPPRAComments@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Administration for Community Living (ACL) is requesting approval to collect data for information collection requirements related to Centers for Independent Living Program Performance Report (CIL PPR) (0985–0061). In the context of ACL, IL programs are supported through funding authorized by the Rehabilitation Act of 1973, as amended (The Act). Title VII, chapter 1 of the Act states the current purpose of the program is to ''promote a philosophy of independent living including a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and system advocacy, in order to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities, and the integration and full inclusion of individuals with disabilities into the mainstream of American society.''

The CIL PPR is submitted annually by all CILs receiving IL Part C funds. The PPRs are used by ACL to assess grantees' compliance with title VII of the Act, and with 45 CFR 1329 of the Code of Federal Regulations and with applicable provisions of the HHS Regulations at 45 CFR part 75. The PPR serves as the primary basis for ACL's monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The PPR also enables ACL to track performance outcomes and efficiency measures of the CIL programs with respect to the annual and long-term performance targets established in compliance with GPRA. The PPR is also used by ACL to design CIL and Statewide Independent Living Council training and technical assistance programs authorized by section 711A and section 721 of the Act.

The CARES Act PPR is submitted annually by all CILs receiving CARES Act funds. The CARES Act requires ACL grantees that receive CARES Act funding to report quarterly, to ACL and to the Pandemic Response Accountability Committee, ''the total amount of large covered funds that the grantee received from ACL; the amount of large covered funds received that were expended or obligated for each project or activity; a detailed list of all projects or activities for which large covered funds were expended or obligated, including the name of the project or activity; a description . . . ; and the estimated number of jobs created or retained by the project or activity, where applicable; and detailed information on any subcontracts or Subgrants . . .'' Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, H.R. 748 15011(a–b), 116th Cong. (2020).

The current version of the CIL PPR (that includes the CARES Act PPR) that OILP is requesting an extension for was approved by OMB; the approval was extended and will expire on January 31, 2022.

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on August 9, 2021 (Vol. 86, Number 2021–16752; pp. 43549–43550).

We received no comments during the 60-day comment period.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: The two-hundred ninety Part C CILs will complete 353 CIL PPRs annually, and it will take an estimated 35 hours per CIL per CIL PPR for an estimated total of 12,355 hours. Two-hundred ninety CILs will each complete CARES Act PPRs, and it will take an estimated forty-six hours per CIL per CARES Act PPR. The two-hundred ninety Part C CILs will take an estimated 13,340 hours to complete CARES Act PPRs. The two-hundred ninety Part C CILs will spend an estimated 25,695 hours completing CIL PPRs and CARES Act PPRs. These burden estimates are based on ACL's estimate of the average time required to collect the information collected in the PPR and feedback from CILs on the time needed to complete the PPR.

Respondent	Data collection activity	Number of respondents	Responses per respondent	Hours per response	Total Annual burden hours
CILs	CIL PPR	353	1	35	12,355
CILs	CARES Act PPR	290	1	46	13,340
CILs	Total		2	81	25,695

Dated: January 12, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00892 Filed 1–18–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0297]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of Salmonella Enteritidis in Shell Eggs During Production; Recordkeeping and Registration Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's recordkeeping and registration requirements for shell egg producers.

DATES: Submit either electronic or written comments on the collection of information by March 21, 2022.

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 March 21, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 21, 2022. 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–2013–N–0297 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of *Salmonella Enteritidis* in Shell Eggs During Production; Recordkeeping and Registration Provisions.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions—21 CFR 118.10 and 118.11

OMB Control Number 0910–0660—Extension

This information collection supports Agency regulations in part 118 (21 CFR part 118), Production, Storage, and Transportation of Shell Eggs, and Form FDA 3733, Shell Egg Producer Registration Form. The Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State'' (section 361(a) of the PHS Act (42 U.S.C. 264(a))). This authority has been delegated to the Commissioner

of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under part 118, shell egg producers are required to implement measures to prevent *Salmonella Enteritidis* (SE) from contaminating eggs on the farm and from further growth during storage and transportation. Shell egg producers also are required to maintain records concerning their compliance with part 118 and to register with FDA. As described in more detail about each information collection provision of part 118, each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all of their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA's regulations requires recordkeeping for all measures the farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are maintained on file at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan.

Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA's regulations requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. The term ''Form FDA 3733'' refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *https://www.access.fda.gov.* We strongly encourage electronic registration because it is faster and more convenient. The system can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer receives confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form FDA 3733 is available for download for registration by mail, fax or CD–ROM. For more information, we invite you to visit our website at *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/shell-egg-producer-registration.*

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our enforcement activities.

Description of Respondents: Respondents to this information collection include farm sites with 3,000 or more egg laying hens that sell raw eggs to the table egg market, other than directly to the consumer.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers [2]	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Refrigeration Records; § 118.10(a)(3)(iv)	2,600	52	135,200	0.5 (30 minutes)	67,600
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (positive) [3].	343	52	17,836	0.5 (30 minutes)	8,918
Egg Testing; § 118.10(a)(3)(vii)	331	7	2,317	8.3	19,231
Environmental Testing; § 118.10(a)(3)(v) [3]	6,308	23	145,084	0.25 (15 minutes)	36,271
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (negative) [3].	5,965	1	5,965	0.5 (30 minutes)	2,983
Prevention Plan Review and Modifications; § 118.10(a)(4)	331	1	331	10	3,310
Chick and Pullet Procurement Records; § 118.10(a)(2)	4,731	1	4,731	0.5 (30 minutes)	2,366
Rodent and Other Pest Control; § 118.10(a)(3)(ii), and Biosecurity Records, § 118.10(a)(3)(i).	9,462	52	492,024	0.5 (30 minutes)	246,012
Prevention Plan Design; § 118.10(a)(1)	350	1	350	20	7,000
Cleaning and Disinfection Records; § 118.10(a)(3)(iii)	331	1	331	0.5 (30 minutes)	166
Total					393,857

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Some records are kept on a by-farm basis and others are kept on a by-house basis.
[3] Calculations include requirements for pullet and layer houses.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates; § 118.11	FDA 3733 [2]	350	1	350	2.3	805
Cancellations; § 118.11	FDA 3733	30	1	30	1	30
Total						835

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term ''Form FDA 3733'' refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov* per § 118.11(b)(1).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimates for the recordkeeping burden and the reporting burden are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

Dated: January 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00863 Filed 1–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Thursday, February 10, 2022, and Friday, February 11, 2022. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Thursday, February 10, 2022, from 10:00 a.m.–3:00 p.m. Eastern Time (ET) and Friday, February 11, 2022, from 10 a.m.–2:30 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* The deadline for registration is 12:00 p.m. ET on February 9, 2022. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the February 10–11, 2022 meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Final evidence-based review report on the Mucopolysaccharidosis type II (MPS II) condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend to the Secretary adding MPS II to the RUSP.

(2) A presentation on phase two of the evidence-based review for Guanidinoacetate methyltransferase (GAMT) deficiency.

(3) An update on the Krabbe disease condition nomination.

(4) A possible vote on whether to move Krabbe disease forward to full evidence-based review.

(5) Overview of ACHDNC consumer-friendly resources.

(6) A presentation on healthy equity in newborn screening.

The agenda for this meeting includes a potential vote which may lead to a decision to recommend a nominated condition (MPS II) to the RUSP. As noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Krabbe disease) to full evidence-based review, and will hear presentations on the evidence-based review for Guanidinoacetate methyltransferase deficiency, any of which may lead to a recommendation to add or not add a condition/conditions to the RUSP at a future time.

Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website listed above.

Members of the public also will have the opportunity to provide comments. Public participants providing oral comments may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Subject to change: Members of the public registered to submit oral public comments on MPS II are tentatively scheduled to provide their statements on Thursday, February 10, 2022. Members of the public registered to provide statements on all other newborn screening related topics are tentatively scheduled for Friday, February 11, 2022. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Friday, February 4, 2022.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–00896 Filed 1–18–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Publication of the Trusted Exchange Framework and Common Agreement

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice.

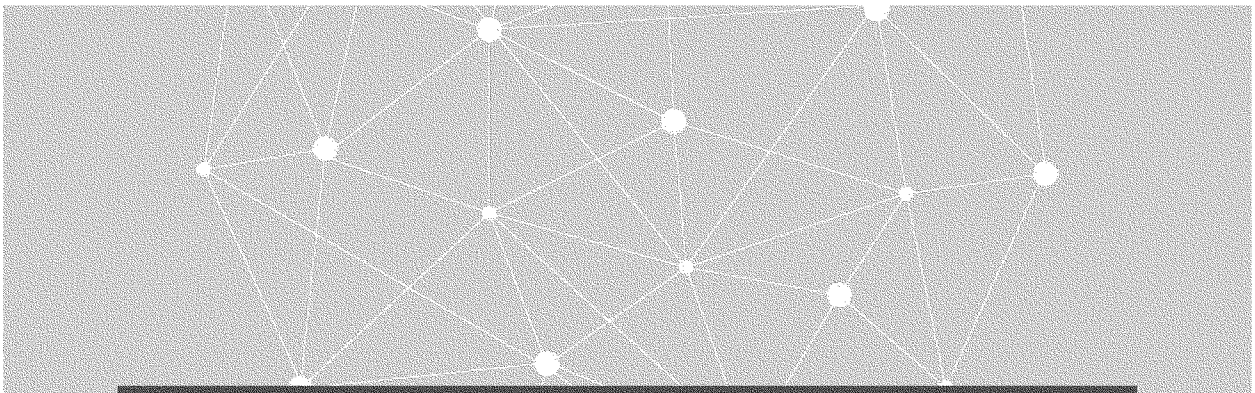
SUMMARY: This notice fulfills an obligation under the Public Health Service Act (PHSA), which requires the

National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public internet website, and in the **Federal Register**, the trusted exchange framework and common agreement developed under the PHSA.

FOR FURTHER INFORMATION CONTACT: Michael L. Lipinski, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION: This notice fulfills the obligation under section 3001(c)(9)(C) of the Public Health Service Act (PHSA) to publish the trusted exchange framework and common agreement (TEFCA), developed under section 3001(c)(9)(B) of the PHSA (42 U.S.C. 300jj–11(c)(9)(B)), in the **Federal Register**. The TEFCA consists of the following two documents:

BILLING CODE 4150–45–P



The Trusted Exchange Framework (TEF): Principles for Trusted Exchange

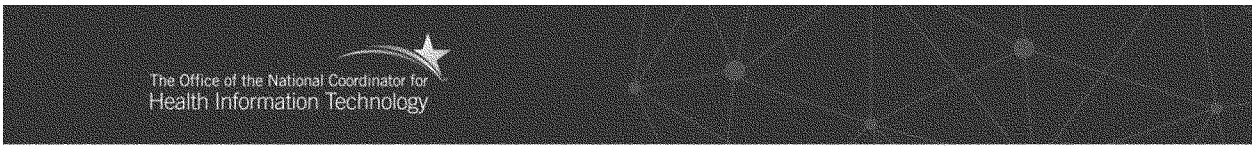
January 2022

This document was published by the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology and was produced at U.S. taxpayer expense.

This document meets the requirement in section 3001(c)(9)(C) of the Public Health Service Act for the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public Internet website, and in the Federal Register, the trusted exchange framework (42 U.S.C. 300jj-11(c)(9)(C)).

The Office of the National Coordinator for Health Information Technology

CONTENTS



Overview and Background

The 21st Century Cures Act[1] (Cures Act) directs the National Coordinator to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally." In January 2018, the Office of the National Coordinator for Health Information Technology (ONC) released the first draft of the Trusted Exchange Framework[2] (TEF Draft 1) for public comment. The TEF Draft 1 included two parts: "Part A — Principles for Trusted Exchange," and "Part B — Minimum Required Terms and Conditions for Trusted Exchange." In April of 2019, ONC released the second draft of the TEF (TEF Draft 2) for public comment, which also included "Part A — Principles for Trusted Exchange" and "Part B — Minimum Required Terms and Conditions for Trusted Exchange."

This document represents the final version of the Trusted Exchange Framework (TEF), titled "The Trusted Exchange Framework: Principles for Trusted Exchange." The policies formerly known as the Minimum Required Terms and Conditions (MRTCs) and the Additional Required Terms and Conditions (ARTCs) are now combined into the Common Agreement. The Common Agreement may be viewed in the Federal Register, on ONC's website, and on the website of The Sequoia Project, Inc., the current entity selected through a competitive process by ONC to serve as the Recognized Coordination Entity (RCE) under a cooperative agreement.[3]

The TEF describes a common set of non-binding, foundational principles for trust policies and practices that can help facilitate exchange among health information networks (HINs). Broad industry alignment with these principles should help facilitate entities' entering into effective contractual relationships for the secure electronic flow of digital health information where and when it is needed. The TEF principles also support the ability of patients (or their legal representatives, which may include caregivers), their health care providers, and other authorized health care stakeholders to electronically access digital health information when and where it is needed most to improve care coordination and quality improvement.

The TEF is built on policy principles that have underpinned ONC's activities and federal health IT policies for over a decade. HINs already follow many of these principles. The inclusion of these principles in the TEF provides a means to further advance their use.

[1] Pub. L. 114–255 (Dec. 13, 2016).
[2] https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf.
[3] https://www.healthit.gov/sites/default/files/page/2019-04/TEFCANOFO%20.pdf.

Principles for Trusted Exchange

Principle 1 — Standardization: HINs should prioritize federally recognized and industry recognized technical standards, policies, best practices, and procedures.

A. HINs should prioritize health information technology standards for interoperability that the U.S. Department of Health & Human Services (HHS) has adopted in regulations, ONC has identified in the Interoperability Standards Advisory (ISA), or a standards developing organization (SDO) accredited by the American National Standards Institute (ANSI) has published.

Even where a statute or regulation does not require it, trusted exchange efforts should adhere to federally adopted health information technology standards for interoperability to support robust and widespread adoption. HINs should first look to standards adopted by HHS for use in Health Insurance Portability and Accountability Act (HIPAA) transactions [4] or use in the ONC Health IT Certification Program [5] (Certification Program), including any updated versions of such adopted standards that ONC has approved for use in the Certification Program through the Standards Version Advancement Process (SVAP),[6] and then those identified in the ISA.[7]

In instances where none of the above references include applicable standards, HINs should then consider voluntary consensus or industry standards that are readily available to all stakeholders and published by SDOs accredited by ANSI. Consistent adherence to standards in the manner described in this paragraph will support improved usability and electronic access to digital health information.

B. HINs should implement technology in a manner that makes it easy to use and allows authorized users to connect to data sources, innovate, and use data to support better, more person-centered care, smarter spending, and healthier people.

HINs should use standards-based technology to electronically exchange digital health information within their own HINs and with other HINs. To minimize variation in how standards are implemented, such technology should be implemented in accordance with authoritative implementation specifications and

[4] The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act administrative simplification of electronic data interchange provisions are implemented by HHS through the National Standards Group at the Centers for Medicare and Medicaid Services (CMS), which adopts certain transaction standards that are required to be used when electronic data are exchanged in support of covered administrative transactions. These transactions include: health care claims or equivalent encounter information; eligibility for a health plan; enrollment and disenrollment in a health plan; health care electronic funds transfers (EFT) and remittance advice; referral certification and authorizations; health care claims status; coordination of benefits; health plan premium payments; and Medicaid pharmacy subrogation. HIPAA covered entities must use the adopted standards, generally either an ASC X12N or NCPDP standard (for certain pharmacy transactions), in conducting transactions.

[5] *https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program*.

[6] ONC Standards Version Advancement Process, *available at* *https://www.healthit.gov/topic/standards-version-advancement-process-svap*.

[7] ONC Interoperability Standards Advisory (ISA), *available at* https://www.healthit.gov/isa/.

best practices published by an applicable SDO. By doing so, HINs should be better able to connect to each other and with their participants.

HINs should, to the extent possible, ensure that the data exchanged within their own network and with other HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels. HINs may consider using tools to support this analysis, such as ONC's Consolidated Clinical Document Architecture (C-CDA) Scorecard tool for testing the technical conformance of C-CDAs[8] and ONC's Inferno Program Edition tool[9] for testing Fast Healthcare Interoperability Resources (FHIR®) APIs.

Principle 2 — Openness and Transparency: HINs should conduct activities openly and transparently, wherever possible.

A. HINs should make terms, conditions, and contractual agreements that govern the exchange of digital health information easily and publicly available.

All parties desiring to electronically exchange digital health information through a HIN should know, prior to engaging with a HIN, the responsibilities of being a participant in that HIN, the information privacy and security protections the HIN requires, as well as its data use and disclosure policies. HINs should make these and other terms and conditions for participating in their network easily and publicly available, meaning readily found on their websites.

B. HINs should specify and have all of its participants agree to the uses and disclosures for exchanging digital health information.

Because HINs are often either HIPAA business associates of covered entities or a business associate subcontractor of a business associate, their Business Associate Agreements (BAAs) specify the uses and disclosures for which their HIN may be used to electronically exchange digital health information.[10] While some HINs currently support many of the uses and disclosures specifically addressed in the HIPAA Privacy Rule,[11] others may only support use and disclosure of digital health information for treatment purposes.

When HINs vary in allowable uses and disclosures in their agreements, the full electronic exchange of digital health information between those HINs is limited. Therefore, HINs should, in compliance with applicable law, specify the minimum set of uses and disclosures they support. These uses and disclosures should be specified in a HIN's legal agreement with its participants or included in a contract addendum if the legal agreement is already in place, made open and transparent, consistent with Principle 2.A, and

[8] ONC Consolidated-Clinical Document Architecture (C-CDA) Scorecard, *https://site.healthit.gov/home*.
[9] ONC Inferno Program Edition, *https://inferno.healthit.gov/inferno/*.
[10] For information about HIPAA covered entities and business associates, *see* 45 CFR 160.103 and *https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html*.
[11] The "HIPAA Privacy Rule" refers to the privacy regulations under HIPAA, 45 CFR part 160 and subparts A and E of part 164.

clearly communicated to relevant parties prior to when digital health information[12] is requested or sent between participants and HINs.

C. HINs should publish, keep current, and make publicly available the HIN's privacy practices.

Ensuring that participants of HINs understand the privacy practices of each HIN will help to build trust that digital health information will be protected and will not be used in ways that they do not expect. Consequently, HINs and their participants should subscribe to the following privacy practices:

(a) HINs must comply with all applicable laws and regulations regarding the use and disclosure of digital health information. When consent or authorization is required by federal or state law, HINs should have policies for where consent and/or authorization is enforced within their architecture.
(b) HINs should clearly specify the minimum set of uses and disclosures for exchanging digital health information and, for non-treatment purposes, limit the use of digital health information to the minimum amount required.
(c) HINs should advance the ability of individuals to electronically access their digital health information through HINs' privacy practices.

These privacy practices are critical to effective data exchange. To further promote transparency, HINs should publish and make publicly available a notice written in plain language, similar to ONC's Model Privacy Notice,[13] that describes their privacy practices regarding the access, exchange, use, and disclosure of digital health information.

D. HINs should establish and, where applicable, conduct any dispute resolution processes in an equitable and transparent manner.

It may be necessary to address behavior that violates data sharing agreements among HINs. HINs should ensure that a dispute resolution process for addressing such violations is clearly defined in their respective agreements and subsequently followed. Such dispute resolution processes should be equitable and transparent to all parties, particularly prior to when a data sharing entity signs an agreement with a HIN that binds that entity to such processes.

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[12] The term "digital" when used throughout this document has its plain meaning (i.e., its dictionary definition). *See* Merriam-Webster.com., *https://www.merriam-webster.com/dictionary/digital* (retrieved Jan. 7, 2022). For example, the phrase "digital health information" refers to information that is neither faxed nor is hard copy health information. Furthermore, the phrase "digital health information" is used to deliberately avoid use of specific regulatory terms for specific types of health information.
[13] ONC Model Privacy Notice, *available at www.healthit.gov/sites/default/files/2018modelprivacynotice.pdf*.

Principle 3 — Cooperation and Non-Discrimination: HINs should collaborate with stakeholders across the continuum of care to electronically exchange digital health information, even when a stakeholder may be a business competitor.

HINs should not seek to gain competitive advantage or discriminate against competitors by limiting access to individuals' digital health information, and HINs should not treat digital health information as an asset that can be restricted in order to obtain or maintain a competitive advantage. For example, HINs should not withhold digital health information requested for permitted treatment, payment, or health care operations purposes from health care providers or health plans that are outside of their preferred referral networks or outside of a value-based payment arrangement. They should not establish internal policies and procedures that result in such improper withholding of information. Likewise, HINs should not implement technology in a manner that improperly limits the sharing of digital health information. HINs should not knowingly make misleading statements regarding privacy or security laws or regulations as a pretext for not sharing digital health information. HINs should practice data reciprocity (e.g., have a willingness to share digital health information themselves as opposed to participating in an exchange relationship only for the purpose of receiving digital health information from others). In addition, fees and other costs should be reasonable and should not be used to interfere with access, exchange, use, or disclosure of digital health information within a HIN or between HINs.

HINs should not use contract provisions or proprietary technology implementations to unduly limit connectivity with other HINs—such as by preventing the appropriate flow of digital health information across technological, geographic, or organizational boundaries for health and care, safety, quality measurement, or payment. At the same time, HINs are subject to applicable law, which includes restrictions or policies that interact with such potential limits to connectivity (including the applicable HIPAA Rules[14] and information blocking regulations[15]).

HINs should not use methods that discourage or impede appropriate digital health information exchange with competitors or potential competitors. This includes throttling the speed with which data is exchanged purely for competitive reasons, unnecessarily limiting the data that are exchanged with health care organizations that may be their competitor or a competitor of one of their participants, or requiring unnecessary testing requirements designed to unfairly deter or discourage connections that do not benefit the HIN.

[14] The term "HIPAA Rules" refers to the HIPAA Privacy, Security, and Breach Notification Rules, 45 CFR parts 160 and 164.
[15] *See* 45 CFR part 171.

Principle 4 — Privacy, Security, and Safety: HINs should exchange digital health information in a manner that supports privacy; ensures data confidentiality, integrity, and availability; and promotes patient safety.

A. HINs should ensure that digital health information is exchanged and used in a manner that promotes safe care and wellness, including consistently and accurately matching digital health information to an individual.

Health plans and most health care providers, and their business associates must follow the HIPAA Rules to safeguard health information. However, digital health information is increasingly collected, shared, or used by new types of organizations that are beyond the traditional health care organizations covered by the HIPAA Rules. Privacy and security should be a foundation for all HINs and HIN participants, including those that are not subject to HIPAA.

Ensuring the confidentiality, integrity, and availability of digital health information is paramount to providing safe care and supporting the health and well-being of all individuals and communities. When digital health information is exchanged, a foundational step to safe care and wellness begins with correctly matching the data to an individual so that care is provided to the correct individual based on accurate information. Generally, sophisticated algorithms that use demographic data for matching are the primary method for automatically connecting data to an individual within a HIN. Demographic data quality heavily influences the accuracy and completeness that any given patient matching method can achieve. To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time digital health information is exchanged. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals to enable exchange in a standard format and to accurately match patient data. Furthermore, HINs and their participants should also work to improve the quality of the demographic data that they hold.[16]

Where possible, standard nomenclatures should be used and exchanged in a data format that is consumable by a receiving system, such as a C-CDA or via FHIR APIs. Further, clinicians should update individuals' digital health information in their health IT systems to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another organization. HINs should utilize testing and onboarding processes for their participants to establish a high level of data quality.

B. Within the context of applicable law, HINs should enforce policies concerning individuals' ability to consent to the access, exchange, or use of their digital health information.

When consent or authorization is required by federal or state law, HINs should have policies addressing how consent and/or authorization is enforced within their architecture. The ability to oversee appropriate electronic capture of an individual's consent or authorization to access, exchange, or use their digital health information will engender trust with other entities seeking to exchange with that network.

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[16] ONC's Patient Demographic Data Quality Framework module is intended to support health systems, large practices, health information exchanges, and payers in improving their patient demographic data quality. *See* https://www.healthit.gov/playbook/pddq-framework/.

Differing state laws affect when HINs must obtain consent or authorization from an individual to access, exchange, or use the individual's digital health information. The Privacy Rule does not require a covered entity or its business associates to obtain an individual's consent or authorization before using or disclosing health information for treatment, payment, and health care operations purposes. While the Privacy Rule generally permits covered health care providers to request consent for those purposes, some federal and state laws may require them to do so before they disclose or exchange an individual's digital health information even for treatment and payment purposes. For example, in the case of records regarding human immunodeficiency virus (HIV), mental health, or genetic testing, state laws may impose a more stringent standard (e.g., requiring consent from the individual) than the Privacy Rule.[17] Thus, HINs should have policies that are sufficiently flexible to address these differing consent and authorization requirements.

Principle 5 — Access: HINs should ensure that individuals and their authorized caregivers have easy access to their digital health information and understand how it has been used or disclosed and HINs should comply with civil rights obligations on accessibility.

A. HINs should not impede or impose any unnecessary barriers to the ability of individuals or their legal representatives to access or direct their digital health information to designated third parties, or to learn how information about them has been accessed or disclosed.

HINs who maintain digital health information should (1) enable individuals, or their legal representatives, to easily and conveniently access their digital health information; (2) enable individuals, or their legal representatives, to direct their digital health information to any recipient they designate; and (3) ensure that individuals, or their legal representatives, have a way to learn how their information is shared and used. This principle is consistent with the Privacy Rule, which generally requires covered entities to provide health information to individuals in the form and format in which they request it, if it is readily producible in that form and format.

The Privacy Rule also requires a covered entity to have a Notice of Privacy Practices available to inform individuals about how health information is used and disclosed by the entity, as well as the individual's rights with respect to their health information.

In accordance with applicable law, HINs should support an individual's decision to access their digital health information through an API-enabled third-party application when the individual has directed the HIN to disclose a copy of that individual's health information to the application.

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[17] Privacy and Security Solutions for Interoperable Health Information Exchange, Report on State Law Requirements for Patient Permissions to Disclose Health Information (Aug. 2009), https://www.healthit.gov/sites/default/files/disclosure-report-1.pdf.

In accordance with federal law, HINs that receive federal funding must ensure accessibility by individuals with disabilities and individuals with limited English proficiency.[18]

B. HINs should not impede or impose any unnecessary barriers to the ability of individuals, or their legal representatives, to learn how their health data has been accessed or disclosed.

It is important for individuals, or their legal representatives, to be able to obtain information about how their digital health information has been accessed, used, and disclosed. As the Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information states in its principle on "Openness and Transparency," "[p]ersons and entities, that participate in a network for the purpose of electronic exchange of individually identifiable health information, should provide reasonable opportunities for individuals to review who has accessed their individually identifiable health information or to whom it has been disclosed, in a readable form and format."[19]

HINs should commit to following this principle and should provide such opportunities to review access histories electronically whenever possible, particularly when an individual makes the request electronically. Providing individuals with transparency on how their data has been accessed, used, and disclosed increases their confidence in the HIN.[20] Again, in accordance with federal law, HINs that receive federal funding must ensure accessibility.

Principle 6 — Equity: HINs should consider the impacts of interoperability on different populations and throughout the lifecycle of the activity.

A. HINs should employ a health equity by design approach and should consider the health equity consequences of policy and technology choices up front.

HINs should adopt standards, policies, and processes that explicitly consider health equity.[21] The COVID-19 pandemic amplified the importance of health equity in health IT. Throughout the pandemic,

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[18] *See, e.g.*, Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d-2000d-7 and its implementing regulation at 45 CFR part 80; Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, and its implementing regulation at 45 CFR part 92; and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, and its implementing regulation at 45 CFR part 84.

[19] Office of the National Coordinator for Health Information Technology, Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information, at 7 (Dec. 15, 2008), *available at* http://www.healthit.gov/sites/default/files/nationwide-ps-framework-5.pdf.

[20] *See* Privacy and Security Solutions for Interoperable Health Information Exchange, Report on State Law Requirements for Patient Permissions to Disclose Health Information (Aug. 2009), https://www.healthit.gov/sites/default/files/disclosure-report-1.pdf.

[21] Exec. Order No. 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/. This Executive Order defines equity as "the consistent and systematic fair, just, and impartial treatment of all

public health authorities faced challenges in receiving the granular data needed on specific communities because of inconsistent and heterogeneous data collection and exchange across public health systems. Organizations on the frontline were often unable to get sufficient information needed for decision-making to support a targeted public health response.

A health equity by design approach means that HINs should identify the health equity considerations at the outset of any policy creation, technology development process, or implementation approach, and should include those as core constructs to identify and address health inequities and disparities.

B. HINs should evaluate interoperability efforts, ensure health equity is being achieved, and adjust when it is not.

Evaluation and analysis provide essential evidence to understand how programs work, for whom, and under what circumstances.[22] Building evidence through evaluation and analysis informs decisions in a range of areas, including budget formation, regulatory development, strategic planning, program implementation, and policy construction.[23]

HINs should plan and budget for evaluation of their trusted exchange efforts during all stages of an exchange activity's life cycle. Such evaluation should follow best practices including, for example, the Centers for Disease Control and Prevention Framework for Program Evaluation in Public Health.[24] Additionally, as part of continuous quality improvement activities,[25, 26, 27] HINs should consider the results of such ongoing evaluation and make changes to improve outcomes, including changes in the domain of equity.

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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."

[22] Adapted from HHS Office of the Assistant Secretary for Planning and Evaluation, Evaluation & Evidence, https://aspe.hhs.gov/evaluation-evidence.

[23] *Id.*

[24] Centers for Disease Control and Prevention, *Framework for Program Evaluation in Public Health*, Morbidity and Mortality Weekly Report, Vol. 48, No. RR-11 (Sept. 17, 1999), *available at* https://www.cdc.gov/mmwr/PDF/rr/rr4811.pdf.

[25] Brian O'Donnell and Vikas Gupta, Continuous Quality Improvement (last updated Apr. 7, 2021), *available at* https://www.ncbi.nlm.nih.gov/books/NBK559239/.

[26] Office of the National Coordinator for Health Information Technology, National Learning Consortium, Continuous Quality Improvement (CQI) Strategies to Optimize your Practice, https://www.healthit.gov/sites/default/files/tools/nlc_continuousqualityimprovementprimer.pdf.

[27] Agency for Healthcare Research and Quality, Health Literacy Universal Precautions Toolkit, 2nd Edition, Plan-Do-Study-Act (PDSA) Directions and Examples, *available at* https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html.

Principle 7 — Public Health: HINs should support public health authorities and population-level use cases to enable the development of a learning health system that improves the health of the population and lowers the cost of care.

A. HINs should enable use cases that advance the mission of public health authorities.

Currently, nationwide networks largely support exchange among health care providers for treatment purposes to the exclusion of other critical use cases such as public health, population health, and research. Whenever possible, and in accordance with applicable law, HINs should support use cases that advance priorities for public health authorities.[28, 29] This includes, for example, electronic case reporting, electronic laboratory reporting, case investigations, syndromic surveillance, immunization reporting, adverse event collection or reporting, product defects, product recalls, and post-marketing surveillance.[30, 31]

B. HINs should advance population-level use cases, including quality improvement and research.

Population-level information is fundamental to providing accountability for health care and to enabling a learning health system. A learning health system is defined as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice.[32] As a result, patients get higher quality, safer, more efficient care, and health care delivery organizations become better places to work.[33]

In alignment with Principle 3.A., HINs should enable data exchange for quality measurement and improvement activities. Providers and health plans may want to work with a HIN, consistent with applicable law, to share digital health information from their health information technology to a qualified

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[28] A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. *See* 45 CFR 164.501. Examples of a public health authority include State and local health departments, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA). Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual's authorization, or for disclosures that are required by other law. *See* 45 CFR 164.502(b). For additional information, *see* https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html.

[29] Office of the National Coordinator for Health Information Technology, Public Health, https://www.healthit.gov/topic/health-it-health-care-settings/public-health.

[30] Centers for Disease Control and Prevention, Public Health Data Interoperability, https://www.cdc.gov/datainteroperability/index.html.

[31] HHS Office of Civil Rights, Public Health, https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html.

[32] HHS Agency for Healthcare Research and Quality, About Learning Health Systems (last reviewed May 2019), https://www.ahrq.gov/learning-health-systems/about.html.

[33] *Id.*

clinical data registry (QCDR),[34] a qualified entity (QE),[35] researchers, another HIN, or a health IT developer providing care coordination or quality measurement services. Health plans, including employer-sponsored group health plans, may wish to work with HINs to, where appropriate, obtain information that would better support operations, including using analytics for services such as assessing individuals' risk, population health analysis, and quality and cost analyses.

HINs should support biomedical research activities where appropriate and permitted by law. Under the Cures Act, the Secretary is required to establish a program to evaluate the potential use of real-world evidence to help support the approval of a new indication for drugs and to help to support or satisfy post-approval study requirements.[36] The U.S. Food and Drug Administration uses real-world data and real-world evidence to monitor postmarket safety and adverse events and to make regulatory decisions.[37] To support these and other related use cases, HINs should support biomedical research through their trusted exchange activities, where appropriate. As with all data access supported by HINs, research use cases must always be conducted in accordance with applicable law, guidelines, and ethical principles and considerations.

[34] A Qualified Clinical Data Registry (QCDR) is a CMS-approved vendor that is in the business of improving health care quality. These organizations may include specialty societies, regional health collaboratives, and large health systems or software vendors working in collaboration with one of these medical entities. *See* *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/A-Brief-Overview-of-Qualified-Clinical-Data-Registries.pdf*.

[35] The CMS Qualified Entity (QE) Program, also known as the Medicare Data Sharing for Performance Measurement Program, enables organizations to receive Medicare claims data under parts A, B, and D for use in evaluating provider performance. Organizations approved as QEs are required to use the Medicare data to produce and publicly disseminate CMS-approved reports on provider performance. *See* *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData*.

[36] Pub. L. 114-255, section 505F.

[37] U.S. Food and Drug Administration, Real World Evidence (content current as of Sept. 30, 2021), *https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence*.

Common Agreement

COMMON AGREEMENT FOR NATIONWIDE HEALTH INFORMATION INTEROPERABILITY

Version 1

January 2022

This document was published by the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology and was produced at U.S. taxpayer expense.

This document meets the requirement in section 3001(c)(9)(C) of the Public Health Service Act for the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public Internet website, and in the Federal Register, the common agreement (42 U.S.C. 300jj-11(c)(9)(C)).

The Common Agreement
for Nationwide Health Information Interoperability

This Common Agreement for Nationwide Health Information Interoperability (the "Common Agreement" or "Agreement") is entered into as of the _____ day of _____, _____ (the "Effective Date"), by and between The Sequoia Project, Inc., a Virginia non-stock corporation, acting as the current Recognized Coordinating Entity as defined below (the "RCE") and _____, a _____ ("Signatory"). RCE and Signatory may also be referred to herein individually as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS, Section 4003 of the 21st Century Cures Act directed the U.S. Department of Health and Human Services (HHS) National Coordinator to, "in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally;"

WHEREAS, this Common Agreement (including the documents incorporated herein by reference) is the common agreement developed pursuant to Section 4003 of the 21st Century Cures Act;

WHEREAS, The Sequoia Project has been selected by the Office of the National Coordinator for Health Information Technology (ONC) to serve as the RCE for purposes of developing, implementing, maintaining, and updating this Common Agreement, including the Qualified Health Information Network (QHIN) Technical Framework, as well as managing the activities associated with the designation of interested health information networks (HINs) as QHINs (as defined and set forth in this Common Agreement);

WHEREAS, Signatory wishes to be designated as a QHIN and has completed the application process toward such designation;

WHEREAS, Signatory must, among other conditions set forth in this Common Agreement, agree to be bound by the terms of this Common Agreement before Signatory may

be designated as a QHIN and, upon signing this Common Agreement, Signatory agrees to be so bound as a Signatory and as a QHIN, if so designated, as the case may be;

NOW, THEREFORE, in consideration of the mutual promises set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, mutually agree as set forth below.

AGREEMENT

1. Definitions and Relevant Terminology

1.1 Defined Terms. Capitalized terms used in this Common Agreement shall have the meaning set forth below. Where a definition includes one or more citations to a statute, regulation, or standard, the definition shall be interpreted to refer to such statute, regulation, or standard as may be amended from time-to-time.

Applicable Law: all federal, state, local, or tribal laws and regulations then in effect and applicable to the subject matter herein. For the avoidance of doubt, federal agencies are only subject to federal law.

Business Associate: has the meaning assigned to such term at 45 CFR § 160.103.

Business Associate Agreement (BAA): a contract, agreement, or other arrangement that satisfies the implementation specifications described within 45 CFR § 164.504(e), as applicable.

Common Agreement: unless otherwise expressly indicated, this document, the QHIN Technical Framework (QTF), all Standard Operating Procedures (SOPs), and all other attachments, exhibits, and artifacts incorporated herein by reference.

Confidential Information:

Any information that is designated as Confidential Information by the person or entity that discloses it (a "Discloser"), or that a reasonable person would understand to be of a confidential nature, and is disclosed to another person or entity (a "Recipient") pursuant to this Common Agreement. For the avoidance of doubt, "Confidential Information" does not include electronic protected health information (ePHI), as defined in this Common Agreement, that is subject to a Business Associate Agreement and/or other provisions of this Common Agreement.

Notwithstanding any label to the contrary, "Confidential Information" does **not** include any information that: (i) is or becomes known publicly through no fault of the Recipient; or (ii) is learned by the Recipient from a third party that the Recipient reasonably believes is entitled to disclose it without restriction; or (iii) is already known to the Recipient before receipt from the Discloser, as shown by the Recipient's written records; or (iv) is independently developed by Recipient without the use of or reference to the Discloser's Confidential Information, as shown by the Recipient's written records, and was not subject to confidentiality restrictions prior to receipt of such information from the Discloser; or (v) must be disclosed under operation of law, provided that, to the extent permitted by Applicable Law, the Recipient gives the Discloser reasonable notice to allow the Discloser to object to such redisclosure, and such redisclosure is made to the minimum extent necessary to comply with Applicable Law.

Connectivity Services: the technical services provided by a QHIN consistent with the requirements of the then-applicable QHIN Technical Framework and pursuant to this Common Agreement with respect to all Exchange Purposes.

Cooperative Agreement: the Cooperative Agreement NAP-AX-19-001 – Trusted Exchange Framework and Common Agreement by and between Sequoia Project, Inc. and HHS, or, if applicable, a successor agreement between Sequoia Project, Inc. and HHS or a successor agreement between a different Recognized Coordinating Entity and HHS.

Covered Entity: has the meaning assigned to such term at 45 CFR § 160.103.

Cybersecurity Council: the council established by the RCE to enhance cybersecurity commensurate with the risks to QHIN-to-QHIN exchange, as more fully set forth in an SOP.

Designation (including its correlative meanings "Designate," "Designated," and "Designating"): the RCE's written confirmation to ONC that Signatory has satisfied all the requirements of the Common Agreement, the QHIN Technical Framework, and all applicable SOPs and is now a QHIN.

Direct Relationship: a relationship between (i) an Individual and (ii) a QHIN, Participant, or Subparticipant, that arises when the QHIN, Participant, or Subparticipant, as applicable, offers services to the Individual in connection with one or more of the Framework Agreements, and the Individual agrees to receive such services.

Disclosure (including its correlative meanings "Disclose," "Disclosed," and "Disclosing"): the release, transfer, provision of access to, or divulging in any manner of TI outside the entity holding the information.

Discovery: for purposes of determining the date on which a TEFCA Security Incident was discovered, the term Discovery shall be determined consistent with 45 CFR § 164.404(a)(2) as if the TEFCA Security Incident were a breach (as defined in 45 CFR § 164.402) except that this term shall also apply to Non-HIPAA Entities.

Dispute: means (i) a disagreement about any provision of this Common Agreement, including any SOP, the QTF, and all other attachments, exhibits, and artifacts incorporated by reference; or (ii) a concern or complaint about the actions, or any failure to act, of Signatory, the RCE, or any other QHIN or another QHIN's Participant(s).

Dispute Resolution Process: has the meaning assigned to such term in Section 15.1 of this Common Agreement.

Downstream Subparticipant: a Subparticipant that has entered into a Downstream Subparticipant Agreement to use the services of another Subparticipant (referred to as the "Upstream Subparticipant") to send and/or receive information as described in Section 9 of this Common Agreement.

Downstream Subparticipant Agreement: an agreement that incorporates all of the Required Flow-Downs of this Common Agreement and is between a Subparticipant (referred to as the "Upstream Subparticipant") and one or more Subparticipants (each a "Downstream Subparticipant"), which enables the Downstream Subparticipant(s) to use the services of the Upstream Subparticipant as described in Section 9 of this Common Agreement to send and/or receive information for one or more Exchange Purposes; provided, however, that any provisions of said agreement that permit or require activities other than those required or permitted by the Common Agreement shall not be deemed part of the Downstream Subparticipant Agreement as defined herein. For example, if the agreement provides for transmission of information for reasons other than the Exchange Purposes, the provisions governing such activities shall not be deemed part of the Downstream Subparticipant Agreement as defined herein. Any Subparticipant may enter into a Downstream Subparticipant Agreement.

Electronic Protected Health Information (ePHI): has the meaning assigned to such term at 45 CFR § 160.103.

Exchange Purpose(s): means the reason, as authorized by this Common Agreement including the Exchange Purposes SOP, for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Authorized Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes SOP, each to the extent permitted under Applicable Law, under all applicable provisions of this Common Agreement, and, if applicable, under the implementation SOP for the applicable Exchange Purpose.

Framework Agreement(s): any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.

FTC Rule: the Health Breach Notification Rule promulgated by the Federal Trade Commission set forth at 16 CFR Part 318.

Government Benefits Determination: a determination made by any federal, state, local, or tribal agency, instrumentality, or other unit of government as to whether an Individual qualifies for government benefits for any purpose other than health care (for example, Social Security disability benefits) to the extent permitted by Applicable Law. Disclosure of TI for this purpose may require an authorization that complies with Applicable Law.

Government Health Care Entity: any agency, instrumentality, or other unit of the federal, state, local, or tribal government to the extent that it provides health care services (e.g., Treatment) to Individuals but only to the extent that it is not acting as a Covered Entity.

Health Care Operations: has the meaning assigned to such term at 45 CFR § 164.501, except that this term shall apply to the applicable activities of a Health Care Provider regardless of whether the Health Care Provider is a Covered Entity.

Health Care Provider: has the meaning assigned to such term in the information blocking regulations at 45 CFR § 171.102 or in the HIPAA Rules at 45 CFR § 160.103.

Health Information Network (HIN): has the meaning assigned to the term "Health Information Network or Health Information Exchange" in the information blocking regulations at 45 CFR § 171.102.

HIPAA: the Health Insurance Portability and Accountability Act of 1996 codified at 42 U.S.C. § 300gg, 29 U.S.C. § 1181 *et seq.*, 42 U.S.C. § 1320d *et seq.*, and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 codified at 42 U.S.C. § 17921 et seq., and 42 U.S.C. § 17931 et seq.

HIPAA Rules: the regulations set forth at 45 CFR Parts 160, 162, and 164.

HIPAA Privacy Rule: the regulations set forth at 45 CFR Parts 160 and 164, Subparts A and E.

HIPAA Security Rule: the regulations set forth at 45 CFR Part 160 and Part 164, Subpart C.

Individual: one or more of the following:

(i) An individual as defined by 45 CFR 160.103;

(ii) Any other natural person who is the subject of the information being Requested, Used, or Disclosed;

(iii) A person who legally acts on behalf of a person described in paragraphs (i) or (ii) of this definition in making decisions related to health care as a personal representative, in accordance with 45 CFR 164.502(g);

(iv) A person who is a legal representative of and can make health care decisions on behalf of any person described in paragraphs (i) or (ii) of this definition; or

(v) An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraphs (i) or (ii) of this section or the individual's estate under Applicable Law.

IAS Provider: Each QHIN, Participant, and Subparticipant that offers Individual Access Services.

Individual Access Services (IAS): with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.

Individually Identifiable: refers to information that identifies an Individual or with respect to which there is a reasonable basis to believe that the information could be used to identify an Individual.

Minimum Necessary: refers to the provision in the HIPAA Rules that, under certain circumstances, requires a Covered Entity or a Business Associate to make reasonable efforts when Using or Disclosing PHI or when Requesting PHI from another Covered Entity or Business Associate to limit PHI to the minimum necessary to accomplish the intended purpose of the Use, Disclosure, or Request. See 45 CFR § 164.502(b) and § 164.514(d).

Non-HIPAA Entity (NHE): a QHIN, Participant, or Subparticipant that is neither a Covered Entity nor a Business Associate under HIPAA with regard to activities under this Common Agreement.

Onboarding: the process Signatory, a Participant, or a Subparticipant must undergo to become a QHIN, Participant, or Subparticipant and operational in the production environment under the Framework Agreement to which it is a party. For Signatory, the Onboarding requirements shall be set forth in the Onboarding & Designation SOP addressing the process toward Designation as a QHIN. For a Participant, the Onboarding requirements shall be set forth in the Participant-QHIN Agreement. For a Subparticipant, the Onboarding requirements shall be set forth in the Subparticipant Agreement or the Downstream Subparticipant Agreement, as applicable.

ONC: the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology.

Organized Health Care Arrangement: has the meaning assigned to such term at 45 CFR § 160.103.

Participant: to the extent permitted by applicable SOP(s), a U.S. Entity regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.

Participant-QHIN Agreement:

An agreement that incorporates all of the Required Flow-Downs of this Common Agreement and is between a QHIN and one or more Participants;

provided, however, that any provisions of said agreement that permit or require activities other than those required or permitted by the Common Agreement shall not be deemed part of the Participant-QHIN Agreement as defined herein. For example, if the agreement provides for transmission of information for reasons other than the Exchange Purposes, the provisions governing such activities shall not be deemed part of the Participant-QHIN Agreement as defined herein.

In the event of any conflict or inconsistency between or among Applicable Law, the Participant-QHIN Agreement, and any other terms and conditions, the following shall be the order of precedence to the extent of such conflict or inconsistency: (i) Applicable Law; (ii) the provisions of the Participant-QHIN Agreement that are Required Flow-Downs under this Common Agreement; (iii) to the extent applicable, the QTF; (iv) to the extent applicable, the SOPs; and (v) any other terms and conditions agreed to by the parties.

Participant-Subparticipant Agreement:

An agreement that incorporates all of the Required Flow-Downs of this Common Agreement and is between a Participant and one or more Subparticipants, which enables the Subparticipant(s) to use the services of the Participant as described in Section 9 of this Common Agreement to send and/or receive information for one or more Exchange Purposes; provided, however, that any provisions of said agreement that permit or require activities other than those required or permitted by the Common Agreement shall not be deemed part of the Participant-Subparticipant Agreement as defined herein. For example, if the agreement provides for transmission of information for reasons other than the Exchange Purposes, the provisions governing such activities shall not be deemed part of the Participant-Subparticipant Agreement as defined herein.

In the event of any conflict or inconsistency between or among Applicable Law, the Participant-Subparticipant Agreement, and any other terms and conditions, the following shall be the order of precedence to the extent of such conflict or inconsistency: (i) Applicable Law; (ii) the provisions of the Participant-Subparticipant Agreement that are Required Flow-Downs under this Common Agreement; (iii) to the extent applicable, the QTF; (iv) to the extent applicable, the SOPs; and (v) any other terms and conditions agreed to by the parties.

Payment: has the meaning assigned to such term at 45 CFR § 164.501.

Privacy and Security Notice: has the meaning assigned to such term in Section 10.3 of this Common Agreement.

Protected Health Information (PHI): has the meaning assigned to such term at 45 CFR § 160.103.

Public Health: with respect to the definition of Exchange Purposes, a Request, Use, Disclosure, or Response permitted under the HIPAA Rules and other Applicable Law for public health activities and purposes involving a Public Health Authority, where such public health activities and purposes are permitted by Applicable Law, including a Use or Disclosure permitted under 45 CFR § 164.512(b) and 45 CFR § 164.514(e). For the avoidance of doubt, a Public Health Authority may Request, Use, and Disclose TI hereunder for the Exchange Purpose of Public Health to the extent permitted by Applicable Law and the Framework Agreements.

Public Health Authority: has the meaning assigned to such term at 45 CFR § 164.501.

QHIN Technical Framework (QTF): the document described in Section 5.2 of this Common Agreement and incorporated by reference into this Common Agreement, as may be amended, that may include: (i) technical requirements, functional requirements, and privacy- and security-related requirements for the exchange of TI between QHINs; (ii) internal-QHIN functional requirements; (iii) technical, privacy, and security flow-down requirements from the QHIN to the Participants and/or Subparticipants (if any) in addition to the privacy and security Required Flow-Downs in the Common Agreement; and (iv) operational requirements that enable the exchange of TI between and among QHINs.

Qualified Health Information Network (QHIN): to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.

RCE Directory Service: a technical service provided by the RCE that enables QHINs, Participants, and Subparticipants to share directory information associated with other QHINs, Participants, and Subparticipants in order to enable the exchange of TI under the Common Agreement. The then-current technical endpoints and other identifying information of QHINs, Participants, and Subparticipants are included and maintained as part of the RCE Directory Service.

Recognized Coordinating Entity (RCE): the entity selected by ONC that will enter into the Common Agreement with QHINs in order to impose, at a minimum, the requirements of the Common Agreement, including the SOPs and the QTF, on the QHINs and administer such requirements on an ongoing basis. The RCE is a Party to this Common Agreement.

Request(s) (including its correlative uses/tenses "Requested" and "Requesting"): the act of asking for information in accordance with the applicable requirements of the Framework Agreements.

Required Flow-Down(s): the rights and obligations set forth within this Common Agreement that Signatory is required to incorporate in its Participant-QHIN Agreements and that Signatory is required to obligate its Participants to include in their Subparticipant Agreements and that Signatory must require Participants to obligate Subparticipants to impose on their Downstream Subparticipants, if any, through their Downstream Subparticipant Agreements. **Provisions of this Common Agreement containing such rights and obligations are identified in the section or applicable subsection title as "(Required Flow-Down(s))."**

Required Information:

Electronic information maintained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement:

(i) that would be ePHI if maintained by a Covered Entity or a Business Associate; and

(ii) regardless of whether the information is or has already been transmitted via QHIN-to-QHIN exchange.

Notwithstanding the foregoing, the following types of information are **not** Required Information:

(a) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; or

(b) psychotherapy notes (as defined at 45 CFR 164.501).

Response(s) (including its correlative uses/tenses "Responded" and "Responding"): the act of providing information or the information provided in accordance with the applicable requirements of the Framework Agreements.

Signatory: the entity that has satisfied Section 4.1 and is a Party to this Common Agreement.

Standard Operating Procedure(s) or **SOP(s):** a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into this Common Agreement to provide detailed information or requirements related to the exchange activities under the Common Agreement, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. SOPs will be adopted to address the application process, the Onboarding process, and other operational processes. Each SOP identifies the relevant group(s) to which the SOP applies, including whether Participants and/or Subparticipants are required to comply with a given SOP. An SOP shall be deemed in effect when adopted pursuant to Section 5.3 of this Common Agreement and listed on a public website.

Subparticipant: to the extent permitted by applicable SOP(s), a U.S. Entity regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either: (i) a Participant-Subparticipant Agreement to use the services of a Participant as described in Section 9 of this Common Agreement to send and/or receive information; or (ii) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used as described in Section 9 of this Common Agreement to send and/or receive information.

TEFCA Information (TI): any information that is exchanged between QHINs for one or more of the Exchange Purposes pursuant to any of the Framework Agreements. As a matter of general policy, once TI is received by a QHIN, Participant, or Subparticipant that is a Covered Entity or Business Associate and is incorporated into such recipient's system of records, the information is no longer TI and is governed by the HIPAA Rules and other Applicable Law.

TEFCA Security Incident(s):

(i) An unauthorized acquisition, access, Disclosure, or Use of unencrypted TI in transit using the Connectivity Services or pursuant to any Framework Agreement between Signatory and its Participants, between Signatory's Participants and their Subparticipants, or between Subparticipants, but **NOT** including the following:

(a) Any unintentional acquisition, access, or Use of TI by a workforce member or person acting under the authority of a QHIN, Participant, or Subparticipant, if such acquisition, access, or Use was made in good faith and within the scope of authority and does not result in further Use or Disclosure in a manner not permitted under Applicable Law and this Common Agreement.

(b) Any inadvertent Disclosure by a person who is authorized to access TI at a QHIN, Participant, or Subparticipant to another person authorized to access TI at the same QHIN, Participant, or Subparticipant, or Organized Health Care Arrangement in which a QHIN, Participant, or Subparticipant participates or serves as a Business Associate, and the information received as a result of such Disclosure is not further Used or Disclosed in a manner not permitted under Applicable Law and this Common Agreement.

(c) A Disclosure of TI where a QHIN, Participant, or Subparticipant has a good faith belief that an unauthorized person to whom the Disclosure was made would not reasonably have been able to retain such information.

(d) A Disclosure of TI that has been de-identified in accordance with the standard at 45 CFR § 164.514(a).

(ii) Other security events (e.g., ransomware attacks), as set forth in an SOP, that prevent the affected QHIN, Participant, or Subparticipant from responding to requests for information as required under this Common Agreement or otherwise adversely affect their participation in QHIN-to-QHIN exchange.

Threat Condition: (i) a breach of a material provision of this Common Agreement that has not been cured within fifteen (15) days of receiving notice of the material breach (or such other period of time to which the Parties have agreed), which notice shall include such specific information about the breach that the RCE has available at the time of the notice; or (ii) a TEFCA Security Incident; or (iii) an event that Signatory, its Participant, or their Subparticipant has reason to believe will disrupt normal exchange under the Framework Agreements, either due to actual compromise of or the need to mitigate demonstrated vulnerabilities in systems or data of the QHIN, Participant, or Subparticipant, as applicable, or could be replicated in the systems, networks, applications, or data of another QHIN, Participant, or Subparticipant.

Treatment: has the meaning assigned to such term at 45 CFR § 164.501.

United States: the 50 States, the District of Columbia, and the territories and possessions of the United States including, without limitation, all military bases or other military installations, embassies, and consulates operated by the United States government.

Unsecured: has the meaning assigned to such term at 45 CFR § 164.402 regarding PHI as if it applied to TI that is Individually Identifiable.

U.S. Entity/Entities: any corporation, limited liability company, partnership, or other legal entity that meets all of the following requirements:

(i) The entity is organized under the laws of a state or commonwealth of the United States or the federal law of the United States and is subject to the jurisdiction of the United States and the state or commonwealth under which it was formed;

(ii) The entity's principal place of business, as determined under federal common law, is in the United States; and

(iii) None of the entity's directors, officers, or executives, and none of the owners with a five percent (5%) or greater interest in the entity, are listed on the *Specially Designated Nationals and Blocked Persons List* published by the United States Department of the Treasury's Office of Foreign Asset Control or on the Department of Health and Human Services, Office of Inspector General's List of Excluded Individuals/Entities.

Upstream Subparticipant: a Subparticipant that provides services to a Downstream Subparticipant pursuant to a Downstream Subparticipant Agreement to send and/or receive information as described in Section 9 of this Common Agreement.

Use(s) (including correlative uses/tenses, such as "Uses," "Used," and "Using"): with respect to TI, means the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

1.2 Common Agreement Terminology.

1.2.1 References to Signatory and QHINs. As set forth in its definition and in the introductory paragraph of this Common Agreement, the term "Signatory" is used to refer to the specific entity that is a Party to this Common Agreement with the RCE. Any and all rights and obligations of a QHIN stated herein are binding upon Signatory upon signing the Common Agreement and are also binding upon all other QHINs. References herein to "other QHINs," "another QHIN," and similar such terms are used to refer to any and all other organizations that have signed the Common Agreement with the RCE.

1.2.2 References to **"(Required Flow-Down(s))"**. Provisions of this Common Agreement containing Required Flow-Downs are identified in the applicable section/subsection title as "**(Required Flow-Down(s))**." For purposes of

implementing the Required Flow-Downs, references in such sections/subsections to "Signatory" shall be interpreted to also mean "Participant(s)" and "Subparticipant(s)," as the case may be. References to "Common Agreement" shall be interpreted to mean the applicable Framework Agreement, as the case may be.

1.2.3 General Rule of Construction. For the avoidance of doubt, a reference to a specific section of the Common Agreement in a particular section does not mean that other sections of this Common Agreement that expressly apply to a QHIN (or to a Participant or a Subparticipant pursuant to a Required Flow-Down) are inapplicable.

2. Incorporation of Recitals. The Recitals set forth above are incorporated into this Common Agreement in their entirety and shall be given full force and effect as if set forth in the body of this Common Agreement.

3. Governing Approach

3.1 Role of the RCE and ONC. ONC was directed by Congress in the 21st Century Cures Act to, "in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." ONC entered into the Cooperative Agreement with the RCE to develop, implement, maintain, and update the Common Agreement.

Under the terms and conditions of the Cooperative Agreement, the RCE is responsible for matters related to the development and operation of the exchange of TI and related activities.

ONC provides oversight of the RCE's work under the Cooperative Agreement. Under the Cooperative Agreement, ONC has the right to review the RCE's conduct, including Designation, corrective action, and/or termination decisions regarding QHINs, the proper execution of nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, and nondiscriminatory treatment by the RCE of QHINs, and whether the RCE has adhered to the

requirements imposed upon it by this Common Agreement. ONC may also address complaints made by a QHIN against the RCE as set forth in Section 15.6.1.

3.2 Participation in Governance. QHINs, Participants, and Subparticipants shall have the opportunity to engage in governance under the Common Agreement.

3.2.1 Role. The Transitional Council and the Governing Council, each as defined below, shall be responsible for the following:

(i) Serving as a resource to the RCE and a forum for orderly and civil discussion of any issues affecting exchange activities or other issues that may arise under the Common Agreement;

(ii) Supporting the RCE in its work to monitor the exchange of TI and other activities under the Common Agreement and serving as a resource to the RCE to identify possible corrective actions for conditions that disrupt exchange activities, including, but not limited to, the following:

(a) Provide advice on issues related to the Onboarding of QHINs;

(b) Assist in evaluating suspected or alleged non-compliance with requirements in this Common Agreement, the SOPs, and the QTF;

(c) Provide input regarding whether to suspend or terminate a QHIN's participation;

(d) Provide advice regarding issues before they become Disputes and are escalated to the formal Dispute Resolution Process; and

(e) Evaluate possible and actual TEFCA Security Incidents, other Threat Conditions, and information and/or recommendations from the Cybersecurity Council.

(iii) Reviewing proposed amendments to the Common Agreement, the QTF, and SOPs and providing feedback to the RCE on the proposed changes;

(iv) Participating in the development of new SOPs and providing feedback to the RCE on the proposed changes;

(v) Participating with the RCE in oversight of the Dispute Resolution Process as set forth in this Common Agreement and the Dispute Resolution Process SOP;

(vi) Informing the RCE on development and updating of the strategic roadmap for exchange activities under the Common Agreement; and

(vii) Advocating for the value of the exchange activities under the Common Agreement and promoting their success.

3.3 Transitional Council. To promote a speedy and efficient ramp-up of the Governing Council, a "Transitional Council" shall serve for a twelve- (12-) month term beginning within thirty (30) days after the RCE announces the first group of QHINs that the RCE Designates. The Transitional Council shall serve as the interim governing body for the activities conducted under the Framework Agreements, as more fully described below and in the Transitional Council SOP.

3.3.1 Transition to the Governing Council:

(i) Transition Plan Development – In addition to the responsibilities listed for participation in governance generally, the Transitional Council shall develop the transition plan to the Governing Council.

(ii) Formation of Caucuses – The RCE shall work with the Transitional Council to form the caucuses described in Section 3.4.1 as part of the transition plan. The caucuses are responsible for identifying individuals to serve on the Governing Council that will be established at the end of the twelve (12) months following the formation of the Transitional Council.

(iii) Transition Timing – At the end of the twelve (12) months following the formation of the Transitional Council, the Governing Council shall assume responsibility for participating in the governance of the exchange and related activities under the Common Agreement with the RCE.

(iv) Continuity – Notwithstanding the twelve- (12-) month term of the Transitional Council, the representatives on the Transitional Council

will continue to serve in their governance role until the representatives of the Governing Council are elected and instated.

3.4 Governing Council. A Governing Council shall be established through election of individual members by each of the caucuses described below by the end of the first twelve (12) months following the date on which the RCE announces the first set of QHINs that it has Designated. The election process and constitution of the Governing Council is more fully set forth in the Governing Council SOP. The Governing Council shall serve as the permanent governing body for activities conducted under the Framework Agreements, as more fully described in the Governing Council SOP.

3.4.1 Caucuses.

(i) QHIN Caucus – Every QHIN shall have the right to appoint one (1) individual who is affiliated with that QHIN, as either an employee or independent contractor, to serve as a member of the QHIN Caucus. The QHIN Caucus will be facilitated by the RCE and shall serve as a forum for QHINs to meet and discuss issues of interest directly related to the exchange of TI and related activities under the Common Agreement.

(ii) Participant/Subparticipant Caucus – Each QHIN shall have the right to appoint up to three (3) individuals who are affiliated with a Participant or a Subparticipant, either as an employee or independent contractor, to serve as a member of the Participant/Subparticipant Caucus. In appointing such individuals, QHINs should consider the composition of their Participants and Subparticipants and should endeavor to select persons who will be representative of the various perspectives of the QHIN's Participant/Subparticipant population. The Participant/Subparticipant Caucus will be facilitated by the RCE and shall provide a forum for Participants to meet and discuss issues of interest directly related to the exchange of TI and related activities under the Common Agreement.

3.5 Advisory Groups. The RCE, in consultation with the Governing Council and ONC, may establish "Advisory Groups," from time to time, for purposes of seeking input from distinct groups of stakeholders that are parties to or affected by activities under the Framework Agreements to better inform the governance process, provide input on certain topics, and promote inclusivity. The process for establishing Advisory Groups and selecting members is set forth in the applicable SOP.

4. QHIN Designation

4.1 Eligibility to be Designated. Signatory affirms that it meets the eligibility criteria listed below and the requirements for demonstrating satisfaction of these criteria that are included in the Onboarding & Designation SOP. Signatory must meet the following criteria at the time Signatory submits an application for Designation:

(i) Signatory must demonstrate that it meets the definition of a U.S. Entity and is not owned or controlled by any non-U.S. person(s) or entity(-ies). The specific, required means to demonstrate this are set forth in an SOP.

(ii) Signatory is able to exchange Required Information, as defined in this Common Agreement. The specific, required means to demonstrate this are set forth in an SOP.

(iii) Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and Designate Signatory under a provisional status, subject to additional monitoring as further provided in the Onboarding & Designation SOP, including additional review during a provisional period.

(iv) Signatory must demonstrate that it has in place, at the time of its application to be Designated, the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its Health Information Network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network. The specific, required means to demonstrate this are set forth in an SOP.

4.2 Affirmation of Application. Signatory represents and warrants that the information in its application is accurate and complete, to the best of its knowledge. Signatory acknowledges that the RCE is relying upon the information in its application to evaluate whether Signatory meets the criteria to be Designated and that violation of this representation and warranty is a material breach of this Common Agreement. If the RCE determines that material information in the application is not accurate or complete, the RCE may refuse to Designate Signatory and withdraw Signatory from Onboarding and terminate this Common Agreement in accordance with 16.2.2.

4.3 QHIN Designation Process. RCE and Signatory will work cooperatively and diligently to allow Signatory to demonstrate that it meets the QHIN eligibility requirements and can comply with the requirements included in this Common Agreement, the QTF, and the SOPs; however, the burden is upon Signatory to demonstrate that it does comply with such requirements. Signatory expressly acknowledges that the RCE is not required to Designate Signatory in the event that Signatory fails to meet the requirements. Signatory agrees that it will not represent that it is a QHIN unless, and until, the RCE formally Designates Signatory. The detailed process for the RCE to review Signatory's application shall be set out in an SOP.

4.4 Formal Designation as a QHIN. If Signatory demonstrates to the RCE that it meets the requirements to be Designated, and affirms that it is a HIN, then the RCE will inform Signatory of its QHIN Designation. The process for Signatory to be formally Designated shall be set out in an SOP.

5. Change Management

5.1 Change Management Framework. The RCE shall coordinate all changes to the Common Agreement, the QTF, and the SOPs in conjunction with ONC. In addition to the activities described below, ONC shall be available in a consultative role throughout the change management process to review any proposed amendments to the Common Agreement, the QTF, and the SOPs as well the adoption of any new SOP and the repeal of any existing SOP. The RCE will work with ONC, the Governing Council, and the QHIN and Participant/Subparticipant Caucuses, as outlined below, to consider amendments to the Common Agreement, the QTF, or the SOPs and the adoption of any new SOP or the repeal of any existing SOP. Provided, however, that the actions described in Sections 5.1 through 5.3 of this Common Agreement by or with respect to the Governing Council, the QHIN Caucus, and the Participant/Subparticipant Caucus, as applicable, shall not be required until the respective body has been established as described in Section 3. Signatory acknowledges that it and the RCE do not have the sole legal authority to agree to

changes to this Common Agreement, the QTF, or the SOPs because ONC will be available in a consultative role throughout the process and must approve all changes, additions, and deletions. The Common Agreement must be the same for all QHINs.

5.2 Amending the Common Agreement or the QTF. The RCE is tasked, under its Cooperative Agreement with ONC, with developing an initial QTF. The QTF Version 1 will be made publicly available prior to the initial QHIN application period (i.e., prior to *anyone* signing the Common Agreement). Proposed amendments to the Common Agreement or QTF may originate from multiple sources, including, but not limited to, ONC, the RCE, the Governing Council, the QHIN Caucus, or the Participant/Subparticipant Caucus. The RCE shall consider all proposed amendments and determine, in conjunction with ONC, whether further action on a proposed amendment is warranted.

5.2.1 If the RCE determines that a proposed amendment warrants further consideration after consultation with ONC, then the RCE will present the proposed amendment to the Governing Council for its review and consideration. The Governing Council will evaluate the proposed amendment and determine whether it will seek feedback from the QHIN Caucus, the Participant/Subparticipant Caucus, or both, as deemed necessary and appropriate. The Governing Council will provide the RCE with written feedback on the proposed amendment, which will include feedback from the QHIN and Participant/Subparticipant Caucuses as applicable and appropriate.

5.2.2 The RCE shall consult with ONC about the Governing Council feedback and determine whether the proposed amendment should proceed. If the RCE decides to proceed with the amendment, it will publish the proposed amendment to the QHIN Caucus for approval by a written vote. An amendment will be approved if both of the following have occurred: (i) at least two-thirds (2/3) of the votes cast by the QHIN Caucus members within the timeframe established by RCE for the voting period are in favor of the proposed amendment, to ensure each QHIN gets one vote but one vote only; and (ii) ONC approves the amendment in writing after approval by the QHIN Caucus as described in subsection (i) of this 5.2.2. Subsection (i) herein shall be satisfied by the RCE's approval of the proposed amendment if, at the time of such approval, the Governing Council and the QHIN Caucus have not yet been established.

5.2.3 The time period for ONC to approve or disapprove of a proposed amendment to the Common Agreement pursuant to subsection 5.2.2(ii)

above shall initially be three (3) months after ONC receives notice from the RCE that the proposed amendment has been approved pursuant to subsection 5.2.2(i) above; provided, however, that ONC may, in its discretion, extend this time for an unlimited number of additional three- (3-) month time periods.

5.2.4 The time period for ONC to approve or disapprove of a proposed amendment to the QTF pursuant to subsection 5.2.2(ii) above shall initially be three (3) months after ONC receives notice from the RCE that the proposed amendment has been approved pursuant to subsection 5.2.2(i) above; provided, however, that ONC may, in its discretion, extend this time for one (1) additional three- (3-) month time period.

5.2.5 If an amendment to the Common Agreement or QTF is approved as described above, the amendment shall become effective on the effective date identified by the RCE as part of the amendment process and shall be binding on Signatory without any further action by Signatory or the RCE. If Signatory is not willing or able to comply with the amendment, then Signatory shall, within fifteen (15) business days of being notified by the RCE that the amendment has been approved by ONC, provide the RCE written notice of termination of this Common Agreement effective no later than the expiration of thirty (30) days from approval of the amendment.

5.2.6 Notwithstanding the foregoing, if the RCE determines, based on advice from legal counsel, that an amendment to the Common Agreement or QTF is required in order for the RCE to remain in compliance with Applicable Law, the RCE is not required to provide QHINs with an opportunity to vote on the amendment. However, the RCE shall still be required to provide sixty (60) days' advance written notice of the amendment and the legal analysis of the need to use this expedited process, unless the RCE would be materially harmed by being out of compliance with Applicable Law if it provided the sixty (60) days' written notice, in which case it will provide as much notice as practicable under the circumstances. Any such amendment to this Common Agreement or the QTF shall be subject to ONC review prior to enactment. Only those amendments that are approved by ONC will be enacted.

5.3 Amending, Adopting, or Repealing an SOP. The RCE is tasked, under its Cooperative Agreement with ONC, with developing an initial set of SOPs that will be considered adopted when initially made publicly available prior to the initial QHIN application period (i.e., prior to *anyone* signing the Common Agreement). The "amendment" process set forth below shall also apply to amending the initial set of SOPs through

adopting one or more new SOPs, repealing an SOP in its entirety, or amending one of the initial SOPs.

5.3.1 Proposed amendments to the SOPs may originate from multiple sources including, but not limited to, ONC, the RCE, the Governing Council, the QHIN Caucus, or the Participant/Subparticipant Caucus. The RCE shall consider all proposed amendments and determine, in consultation with ONC, whether further action on a proposed amendment is warranted.

5.3.2 If the RCE determines that a proposed amendment warrants further consideration after consultation with ONC, then the RCE will present the proposed amendment to the Governing Council for its review and consideration. The Governing Council will evaluate the proposed amendment and determine whether it will seek feedback from the QHIN Caucus, the Participant/Subparticipant Caucus, or both, as deemed necessary and appropriate. The Governing Council will evaluate proposed amendments in a timely manner and provide the RCE with written feedback on the proposed amendment.

5.3.3 The RCE shall consult with ONC about the Governing Council feedback and determine whether the proposed amendment should proceed. If the RCE decides to proceed with the amendment, it will publish the proposed amendment to the QHIN Caucus and the Participant/Subparticipant Caucus for approval by a written vote. An amendment will be approved if both of the following have occurred: (i) at least two-thirds (2/3) of the votes cast by the QHIN Caucus and at least two-thirds (2/3) of the votes cast by the Participant/Subparticipant Caucus within the timeframe established by RCE for the voting period are in favor of the proposed amendment; and (ii) ONC approves the amendment in writing after approval by the QHIN Caucus and the Participant/Subparticipant Caucus as described in subsection (i) of this 5.3.3. Subsection (i) herein shall be satisfied by the RCE's approval of the proposed amendment if, at the time of such approval, the QHIN Caucus and the Participant/Subparticipant Caucus have not yet been established.

5.3.4 The time period for ONC to approve or disapprove of a proposed amendment to an SOP pursuant to subsection 5.3.3(ii) above shall initially be three (3) months after ONC receives notice from the RCE that it has been approved pursuant to subsection 5.3.3(i) above or subsection 5.3.5(i) below; provided, however, that: (a) ONC may, in its discretion, extend this time for one (1) additional three- (3-) month time period; and (b) if ONC, in addition, determines in its reasonable discretion that the amendment affects or may

be contrary to an ONC required policy or another policy of the Department of Health and Human Services or any Applicable Law, ONC may extend this time for an unlimited number of additional three- (3-) month time periods.

5.3.5 Notwithstanding the process set forth in 5.3.3(i), if the proposed amendment will not have a material impact on any Participants or Subparticipants, the RCE may publish the proposed amendment to the QHIN Caucus only, whereby the amendment will be approved if both of the following have occurred: (i) at least two-thirds (2/3) of the votes cast by the QHIN Caucus within the timeframe established by RCE for the voting period are in favor of the proposed amendment; and (ii) ONC approves the amendment in writing after approval by the QHIN Caucus as described in subsection (i) of this 5.3.5. Subsection (i) herein shall be satisfied by the RCE's approval of the proposed amendment if, at the time of such approval, the QHIN Caucus has not yet been established. The RCE will determine an effective date for the approved amendment subject to approval of ONC.

5.3.6 Notwithstanding the foregoing, if the RCE determines, based on advice from legal counsel, that an amendment to an SOP is required in order for the RCE to remain in compliance with Applicable Law, the RCE is not required to provide the QHIN Caucus or the Participant/Subparticipant Caucus with an opportunity to vote on the amendment. However, the RCE shall still be required to provide sixty (60) days' advance written notice of the amendment and the legal analysis of the need to use this expedited process, unless the RCE would be materially harmed by being out of compliance with Applicable Law if it provided the sixty (60) days' written notice, in which case the RCE will provide as much notice as practicable under the circumstances. Any such amendment to an SOP shall be subject to ONC review prior to enactment. Only those amendments that are approved by ONC will be enacted.

5.4 Voting Method. For purposes of the voting process set forth in this Section 5, the phrase "written vote" includes any process by which there is a voting record, which may include voting by electronic means.

6. Cooperation and Non-Discrimination

6.1 Cooperation **(Required Flow-Down)**. Signatory understands and acknowledges that numerous activities with respect to this Common Agreement will likely involve other QHINs and their respective Participants and Subparticipants, as well as employees,

agents, third-party contractors, vendors, or consultants of each of them. To the extent not in violation of Applicable Law, Signatory shall, and shall also require that its Participants and their Subparticipants incorporate the following obligations into all Framework Agreements to which they are a party, if any:

(i) Respond in a timely manner, as may be further provided in an SOP, to inquiries from the RCE or other QHINs about possible issues related to their exchange of information under the Common Agreement;

(ii) Participate collaboratively in discussions coordinated by the RCE to address differing interpretations of requirements in this Common Agreement, the QTF, or any SOP prior to pursuing the Dispute Resolution Process;

(iii) Make reasonable efforts to notify the RCE and other QHINs, as appropriate, when persistent and widespread connectivity failures are occurring with Signatory or its Participants or their Subparticipants, so that all those affected can investigate the problems and identify the root cause(s) of the connectivity failures;

(iv) Work cooperatively, including, without limitation, facilitating contact between other QHINs or their Participants or their Subparticipants and Signatory's Participants or their Subparticipants, to address the root cause(s) of persistent and widespread connectivity failures;

(v) Provide information (or require its Participants to provide information or to require their Subparticipants to do so) to other QHINs in support of collaborative efforts to resolve issues or Disputes, provided that such information is subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any reasonably foreseeable litigation or protecting Confidential Information;

(vi) Provide information to aid the efforts of other QHINs or their respective Participants or Subparticipants to understand, contain, and mitigate a TEFCA Security Incident at the request of such other QHINs or their respective Participants or Subparticipants, provided that such information is subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any reasonably foreseeable litigation or protecting Confidential Information; and

(vii) Subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any reasonably foreseeable litigation or protecting Confidential Information, disclose to the RCE information that Signatory, or its Participants or their Subparticipants, may have that relates to the following:

(a) cybersecurity risk information sharing programs; or

(b) specific, identified security flaws in the operation of the QHIN or its Participants or their Subparticipants that may require the QHIN or its Participants or their Subparticipants to take specific steps to protect the security of their information technology systems and would not otherwise fall into subsection (a).

In no case shall Signatory be required to disclose TI or other information in violation of Applicable Law. In seeking cooperation, Signatory shall make all reasonable efforts to accommodate the other QHIN's(') schedules and reasonable operational concerns. The costs of cooperation to Signatory shall be borne by Signatory and shall not be charged to the RCE or other QHINs. Nothing in this Section 6.1 shall modify or replace the TEFCA Security Incident notification obligations under Section 12.3 and, if applicable, Section 10.5.3 of this Common Agreement.

6.2 Non-Discrimination.

6.2.1 Prohibition Against Exclusivity **(Required Flow-Down)**. Neither Signatory nor the RCE shall prohibit or attempt to prohibit any QHIN, Participant, or Subparticipant from joining, exchanging with, conducting other transactions with, or supporting any other networks or exchange frameworks, using services *other than* the Connectivity Services, concurrently with the QHIN's, Participant's, or Subparticipant's participation in exchange activities conducted under the Framework Agreements.

6.2.2 No Discriminatory Limits on Exchange of TI **(Required Flow-Down)**. Signatory shall not impede the exchange of information as permitted or required under the applicable Framework Agreements or limit interoperability with any other QHIN, Participant, Subparticipant, or Individual in a discriminatory manner. As used in this Section 6.2.2, a "discriminatory manner" means

action that is inconsistently taken or not taken with respect to any similarly situated QHIN, Participant, Subparticipant, Individual, or group of them, whether it is a competitor, or whether it is affiliated with or has a contractual relationship with any other entity, or in response to an event. Notwithstanding the foregoing, limitations, load balancing of network traffic, or other activities, protocols, or rules shall not be deemed discriminatory to the extent that they: (i) satisfy the requirements of the exception set forth in 45 CFR 171.205; and/or (ii) are based on a reasonable and good-faith belief that the other entity or group has not satisfied or will not be able to satisfy the applicable terms hereof (including compliance with Applicable Law) in any material respect, including, if applicable, any Required Flow-Down(s). One QHIN suspending its exchange activities with another QHIN in accordance with Section 16.4.2 shall not be deemed discriminatory.

6.2.3 Updates to Connectivity Services. In revising and updating its Connectivity Services from time to time, Signatory will use commercially reasonable efforts to do so in accordance with generally accepted industry practices and implemented in a non-discriminatory manner; provided, however, this provision shall not apply to limit modifications or updates to the extent that such revisions or updates are required by Applicable Law or implemented to respond promptly to newly discovered privacy or security threats.

6.2.4 Notice of Updates to Connectivity Services. Signatory shall implement a reporting protocol to provide reasonable prior written notice of all modifications or updates of its Connectivity Services to all other QHINs if such revisions or updates are expected to adversely affect the exchange of TI between QHINs or require changes in the Connectivity Services of any other QHIN, regardless whether they are necessary due to Applicable Law or newly discovered privacy or security threats.

7. Confidentiality and Accountability

7.1 Confidential Information **(Required Flow-Down)**. Signatory and RCE each agree to use all Confidential Information received pursuant to this Common Agreement only as authorized in this Common Agreement and any applicable SOP(s) and solely for the purposes of performing its obligations under this Common Agreement or the proper exchange of information under the Common Agreement and for no other purpose. Each Party may act as a Discloser and a Recipient, accordingly. A Recipient will disclose the Confidential Information it receives only to its employees, subcontractors, and agents who require such knowledge and use in the ordinary

course and scope of their employment or retention and are obligated to protect the confidentiality of the Discloser's Confidential Information in a manner substantially equivalent to the terms required herein for the treatment of Confidential Information. Otherwise, a Recipient agrees not to disclose the Confidential Information received to anyone except as permitted under this Common Agreement.

7.2 QHIN Accountability.

7.2.1 Statement of General Principle. To the extent not prohibited by Applicable Law, Signatory shall be responsible for its acts and omissions, and the acts or omissions of its Participants and their Subparticipants, but not for the acts or omissions of any other QHINs or their Participants or Subparticipants. **For the avoidance of doubt, a Signatory that is also a governmental agency or instrumentality shall not be liable to the extent that the Applicable Law that governs Signatory does not expressly waive Signatory's sovereign immunity.** Notwithstanding any provision in this Common Agreement to the contrary, Signatory shall not be liable for any act or omission if a cause of action for such act or omission is otherwise prohibited by Applicable Law. This section shall not be construed as a hold-harmless or indemnification provision.

7.2.2 Harm to RCE. Subject to Sections 7.3 and 7.4 of this Common Agreement that exclude certain types of damages or limit overall damages, Signatory shall be responsible for harm suffered by the RCE to the extent that the harm was caused by Signatory's breach of this Common Agreement and/or any applicable SOP.

7.2.3 Harm to Other QHINs. Subject to Section 7.4 of this Common Agreement, which excludes certain types of damages or limits overall damages, Signatory shall be responsible for harm suffered by another QHIN to the extent that the harm was caused by Signatory's breach of this Common Agreement and/or any applicable SOP.

7.3 RCE Accountability. Signatory will not hold the RCE, or anyone acting on its behalf, including but not limited to members of the Governing Council, Transitional Council, Caucuses, Cybersecurity Council, and any Advisory Group, work group, or subcommittee, its contractors, employees, or agents liable for any damages, losses, liabilities, or injuries arising from or related to this Common Agreement, except to the extent that such damages, losses, liabilities, or injuries are the direct result of

the RCE's breach of this Common Agreement. This section shall not be construed as a hold-harmless or indemnification provision.

7.4 LIMITATION ON LIABILITY. **NOTWITHSTANDING ANYTHING IN THIS COMMON AGREEMENT TO THE CONTRARY, IN NO EVENT SHALL EITHER THE RCE'S OR SIGNATORY'S TOTAL LIABILITY TO EACH OTHER AND ALL OTHER QHINS ARISING FROM OR RELATING TO THIS COMMON AGREEMENT EXCEED AMOUNTS EQUAL TO TWO MILLION DOLLARS ($2,000,000) PER INCIDENT AND FIVE MILLION DOLLARS ($5,000,000) AGGREGATE PER ANNUM OR SUCH OTHER AMOUNTS AS STATED IN A THEN-IN-EFFECT SOP, IN ORDER TO ALLOW FOR THE PERIODIC ADJUSTMENT OF THIS LIABILITY LIMIT OVER TIME WITHOUT THE NEED TO AMEND THIS COMMON AGREEMENT. THIS AND ANY SUCH ADJUSTED LIMITATION ON LIABILITY SHALL APPLY REGARDLESS OF WHETHER A CLAIM FOR ANY SUCH LIABILITY OR DAMAGES IS PREMISED UPON BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER THEORIES OF LIABILITY, EVEN IF SUCH PARTY HAS BEEN APPRISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OCCURRING. IF SIGNATORY IS A GOVERNMENT AGENCY OR A GOVERNMENT INSTRUMENTALITY UNDER FEDERAL LAW, STATE LAW, LOCAL LAW, OR TRIBAL LAW AND IT IS PROHIBITED FROM LIMITING ITS RECOVERY OF DAMAGES FROM A THIRD PARTY UNDER APPLICABLE LAW, THEN THIS SECTION SHALL NOT APPLY TO EITHER SIGNATORY OR THE RCE. NOTHING IN THIS SECTION 7.4 OF THIS COMMON AGREEMENT SHALL BE CONSTRUED TO CREATE LIABILITY FOR A GOVERNMENTAL AGENCY OR INSTRUMENTALITY OR OTHERWISE WAIVE SOVEREIGN IMMUNITY.**

8. RCE Directory

8.1 Access to the RCE Directory Service. The RCE shall provide Signatory with access to the RCE Directory Service once Signatory has been approved for such access by the RCE. The timeframes and requirements for access to the RCE Directory Service and use of the RCE Directory Service are set out in the QTF and the Onboarding & Designation SOP.

8.2 Utilization of the RCE Directory Service **(Required Flow-Down)**. The RCE Directory Service shall be used by Signatory and its Participants and their Subparticipants to create and maintain operational connectivity under the Common Agreement. The RCE is providing Signatory with access to, and the right to use, the RCE Directory Service on the express condition that Signatory only use and disclose information contained in the RCE Directory Service as necessary to advance the intended use of the RCE Directory Service or as required by Applicable Law. For example, Signatory is permitted to disclose information contained in the RCE Directory Service to the

workforce members of its Participant's or Subparticipant's health information technology vendor who are engaged in assisting the Participant or Subparticipant with establishing and maintaining connectivity via this Common Agreement and other Framework Agreements. Further, Signatory shall not use the information contained in the RCE Directory Service for marketing or any form of promotion of its own products and services, unless such use or disclosure is primarily part of an effort by Signatory to expand, or otherwise improve, connectivity via the Common Agreement, and any promotion of Signatory's own products or services is only incidental to that primary purpose. In no event shall Signatory use or disclose the information contained in the RCE Directory Service in a manner that should be reasonably expected to have a detrimental effect on ONC, the RCE, other QHINs and/or their Participants or Subparticipants, or any other individual or organization. For the avoidance of doubt, information contained in the RCE Directory is Confidential Information except to the extent such information meets one of the exceptions to the definition of Confidential Information.

8.3 No Duplicative Entries. Before listing any entity in the RCE Directory Service under Signatory as the QHIN for that Participant or Subparticipant, Signatory must confirm that the Participant or Subparticipant, as the case may be, is not already listed in the RCE Directory Service as a Participant of, or a Subparticipant under, another QHIN. Signatory shall not list in the RCE Directory Service any such duplicative entry as a Participant or Subparticipant of Signatory. Signatory shall not prevent a Participant or Subparticipant from changing the QHIN through which the Participant or Subparticipant engages in exchange under a Framework Agreement.

8.4 Maintenance of RCE Directory Service. The RCE shall provide and maintain the RCE Directory Service on a continuous basis, taking all necessary steps to maintain nominal levels of performance and responsiveness, no less than 99.9% of the time. Communication regarding planned and unplanned downtime should be published to all Participants and Subparticipants promptly, in accordance with generally accepted industry service levels, to ensure that there will be no lapses in service that will materially disrupt the operations of Signatory and other QHINs.

9. TEFCA Exchange Activities

In addition to the requirements below, a QHIN, Participant, or Subparticipant may only Request information under the applicable Framework Agreement for a specific Exchange Purpose if the QHIN, Participant, or Subparticipant is the type of person or entity that is described in the definition of the applicable Exchange Purpose. Such a QHIN, Participant, or Subparticipant may use a Business Associate, agent, or contractor to make such a Request,

Use, or Disclosure for the applicable Exchange Purpose. For example, only a Health Care Provider as described in the definition of Treatment (or a Business Associate, agent, or contractor acting on that Health Care Provider's behalf) may Request information for the Exchange Purpose of Treatment.

This Common Agreement specifies, among other things, the reasons for which information may be Requested and transmitted from one QHIN to another QHIN. Participants and Subparticipants should understand that, despite their participation under a Framework Agreement, QHINs are prohibited from engaging in QHIN-to-QHIN exchange for any purpose other than an Exchange Purpose under this Common Agreement. The RCE recognizes that Signatory may participate in other health information exchange networks and Signatory's Participants and their Subparticipants also likely participate in other networks, as well as non-network information exchange. This Common Agreement does not affect these other activities or the reasons for which Participants and Subparticipants may request and exchange information within their networks and/or subject to other agreements. Such activities are not in any way limited by the Framework Agreements.

9.1 Utilization of Connectivity Services. Signatory may not utilize the Connectivity Services for any purpose(s) other than the Exchange Purposes. Signatory is responsible for verifying the conformance of all transactions initiated by Signatory's Participants and their Subparticipants prior to transmission via QHIN-to-QHIN exchange, as set forth in the QTF. For the avoidance of doubt, a QHIN may only use the Connectivity Services to initiate a transaction as directed by its Participants or their Subparticipants or if the QHIN itself is authorized under the asserted Exchange Purpose.

9.2 Uses **(Required Flow-Down)**. Signatory may Use TI in any manner that: (i) is not prohibited by Applicable Law; (ii) is consistent with Signatory's Privacy and Security Notice, if applicable; and (iii) is in accordance with Sections 11 and 12 of this Common Agreement, if applicable.

9.3 Disclosures **(Required Flow-Down)**. Signatory may Disclose TI provided such Disclosure: (i) is not prohibited by Applicable Law; (ii) is consistent with Signatory's Privacy and Security Notice, if applicable; and (iii) is in accordance with Sections 11 and 12 of this Common Agreement, if applicable.

9.4 Responses **(Required Flow-Downs)**. Signatory must support **all** Exchange Purposes and must Respond to all Exchange Purposes that are identified as "required" in the Exchange Purposes SOP. Signatory must provide all Required Information that is relevant for a required Exchange Purpose, as may be further specified in an implementation SOP for the applicable Exchange Purpose, in Response to a Request

transmitted via QHIN-to-QHIN exchange, unless providing the Required Information is prohibited by Applicable Law or this Common Agreement or if not providing the Required Information is consistent with all Applicable Law and this Common Agreement.

9.4.1 Exceptions to Required Responses. Notwithstanding the foregoing, Signatory is **permitted but not required** to Respond to a Request transmitted via QHIN-to-QHIN exchange in the circumstances set forth in 9.4.1(i)-(vi) below, provided the Response: (a) is not prohibited by Applicable Law; (b) is consistent with Signatory's Privacy and Security Notice, if applicable; and (c) is in accordance with this Common Agreement.

(i) If Signatory is a Public Health Authority;

(ii) If Signatory utilizes the Government Benefits Determination Exchange Purpose, including such an agency's agent(s)/contractor(s);

(iii) If the reason asserted for the Request is Individual Access Services and the information would not be required to be provided to an Individual pursuant to 45 CFR § 164.524(a)(2), regardless of whether Signatory is a NHE, a Covered Entity, or a Business Associate;

(iv) If the Requested information is not Required Information, provided such response would not otherwise violate the terms of this Common Agreement;

(v) If Signatory is a federal agency, to the extent that the Requested Disclosure of Required Information is not permitted under Applicable Law (e.g., it is Controlled Unclassified Information as defined at 32 CFR Part 2002, and the party requesting it does not comply with the applicable policies and controls that the federal agency adopted to satisfy its requirements); or

(vi) If the Exchange Purpose is authorized but not required at the time of the Request, either under this Common Agreement or the Exchange Purposes SOP.

9.5 Special Legal Requirements **(Required Flow-Down)**. If and to the extent Applicable Law requires that an Individual either consent to, approve, or provide an

authorization for the Use or Disclosure of that Individual's information to Signatory, such as a more stringent state law relating to sensitive health information, then Signatory shall refrain from the Use or Disclosure of such information in connection with this Common Agreement unless such Individual's consent, approval, or authorization has been obtained consistent with the requirements of Applicable Law and Section 11 of this Common Agreement, including without limitation communicated pursuant to the process described in the QTF. Copies of such consent, approval, or authorization shall be maintained and transmitted pursuant to the process described in the QTF by whichever party is required to obtain it under Applicable Law, and Signatory may make such copies of the consent, approval, or authorization available electronically to any QHIN, Participant, or Subparticipant in accordance with the QTF and to the extent permitted by Applicable Law. Signatory shall maintain written policies and procedures to allow an Individual to revoke such consent, approval, or authorization on a prospective basis. If Signatory is an IAS Provider, the foregoing shall not be interpreted to modify, replace, or diminish the requirements set forth in Section 10 of this Common Agreement for obtaining an Individual's express written consent.

10. Individual Access Services (Required Flow-Downs, *if Offering Individual Access Services*)

Nothing in the Privacy and Security Notice or in the Individual's written consent collected by Signatory who is an IAS Provider pursuant to Section 10.2 and Section 10.3 may contradict or be inconsistent with any applicable provision of Sections 10 or 11.

10.1 Individual Access Services (IAS) Offering(s) **(Required Flow-Down)**. Signatory may elect to offer Individual Access Services to any Individual in accordance with the requirements of this section and in accordance with all other provisions of this Common Agreement. Nothing in this Section 10 shall modify, terminate, or in any way affect an Individual's right of access under the HIPAA Privacy Rule at 45 CFR 164.524 with respect to any QHIN, Participant, or Subparticipant that is a Covered Entity or a Business Associate. Nothing in this Section 10 of this Common Agreement shall be construed as an exception or excuse for any conduct by the Signatory that meets the definition of information blocking in 45 CFR 171.103.

10.2 Individual Consent **(Required Flow-Down)**. The Individual requesting Individual Access Services shall be responsible for completing Signatory's own supplied form for obtaining Individual express consent in connection with the Individual Access Services, as set forth below. Signatory may implement secure electronic means

(e.g., secure e-mail, secure web portal) by which an Individual may submit such written consent.

10.3 Written Privacy and Security Notice and Individual Consent **(Required Flow-Downs)**.

10.3.1 If Signatory offers Individual Access Services, it must develop and make publicly available a written privacy and security notice (the "Privacy and Security Notice"). The Privacy and Security Notice must:

(i) Be publicly accessible and kept current at all times, including updated versions;

(ii) Be shared with an Individual prior to the Individual's use/receipt of services from Signatory;

(iii) Be written in plain language and in a manner calculated to inform the Individual of such privacy practices;

(iv) Include a statement regarding whether and how the Individual's TI may be accessed, exchanged, Used, and/or Disclosed by Signatory or by other persons or entities to whom/which Signatory Discloses or provides access to the information, including whether the Individual's TI may be sold at any time (including the future);

(v) Include a statement that Signatory is required to act in conformance with the Privacy and Security Notice and must protect the security of the information it holds in accordance with Section 10 of this Common Agreement;

(vi) Include information regarding whom the Individual may contact within Signatory for further information regarding the Privacy and Security Notice and/or with privacy-related complaints;

(vii) Include a requirement by Signatory to obtain express written consent to the terms of the Privacy and Security Notice from the Individual prior to the access, exchange, Use, or Disclosure (including sale) of the Individual's TI, other than Disclosures that are required by Applicable Law;

(viii) Include information on how the Individual may revoke consent;

(ix) Include an explanation of the Individual's rights, including, at a minimum, the rights set forth in Section 10.4, below;

(x) Include a disclosure of any applicable fees or costs related to IAS including the exercise of rights under Section 10.4 of this Common Agreement; and

(xi) Include an effective date.

The implementation of such Privacy and Security Notice requirements shall be set forth in the IAS SOP. If Signatory is a Covered Entity, then a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520 **and** meets the requirement of 10.3.1(iv) above can satisfy the Privacy and Security Notice requirements. Nothing in this Section 10.3 reduces a Covered Entity's obligations under the HIPAA Rules.

10.3.2 If Signatory is an IAS Provider, it must collect the Individual's written consent as required under Section 10.3.1(vii) of this Common Agreement at the outset of the Individual's first use of the Individual Access Services and with any material change in the applicable Privacy and Security Notice.

10.4 Individual Rights **(Required Flow-Down)**. Individuals have, and must be clearly informed of, the following rights:

(i) The right to require that **all** of their Individually Identifiable information maintained by Signatory as an IAS Provider be deleted unless such deletion is prohibited by Applicable Law; provided, however, that the foregoing shall not apply to Individually Identifiable information contained in audit logs.

(ii) The right to an export of their Individually Identifiable information in a computable format, including the means to interpret such information.

The rights described in this Section 10.4 shall control over any inconsistent provisions in Section 11.

10.5 Additional Security Requirements for IAS Providers **(Required Flow-Downs)**. In addition to meeting the applicable security requirements set forth in Section 12, if Signatory is an IAS Provider it must further satisfy the requirements of this subsection.

10.5.1 Scope of Security Requirements. If Signatory is an IAS Provider it must comply with the applicable security requirements set forth in this Common Agreement and the security SOPs for **all** Individually Identifiable information they hold, regardless of whether such information is TI.

10.5.2 Encryption. If Signatory is an IAS Provider it is required to encrypt **all** Individually Identifiable information held by Signatory, both in transit and at rest, regardless of whether such data are TI.

10.5.3 TEFCA Security Incident Notice to Affected Individuals. Each Signatory that is an IAS Provider must notify each Individual whose TI has been or is reasonably believed to have been affected by a TEFCA Security Incident involving the IAS Provider. Such notification must be made without unreasonable delay and in no case later than sixty (60) days following Discovery of the TEFCA Security Incident. The notification required under this section must be written in plain language and shall include, to the extent possible:

(i) A brief description of what happened, including the date of the TEFCA Security Incident and the date of its Discovery, if known;

(ii) A description of the type(s) of Unsecured TI involved in the TEFCA Security Incident (such as whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(iii) Any steps Individuals should take to protect themselves from potential harm resulting from the TEFCA Security Incident;

(iv) A brief description of what the Signatory involved is doing to investigate the TEFCA Security Incident, to mitigate harm to Individuals, and to protect against any further TEFCA Security Incidents; and

(v) Contact procedures for Individuals to ask questions or learn additional information related to the TEFCA Security Incident, which shall include a telephone number (toll-free), e-mail address, and website with contact information and/or a contact form for the IAS Provider.

To the extent Signatory is already required by Applicable Law to notify an Individual of an incident that would also be a TEFCA Security Incident, this section does not require duplicative notification to that Individual.

10.6 Survival for IAS Providers **(Required Flow-Down)**. The following minimum provisions and their respective minimum time periods shall continue to apply to Signatory to the extent that it is an IAS Provider and survive expiration or termination of the applicable Framework Agreement under which Individual Access Services were provided for the time periods and to the extent described below.

10.6.1 The following Section 10 provisions shall survive the expiration or termination of the applicable Framework Agreement until expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under Subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual for whom Individual Access Services were provided, even if the information to which the provisions apply is not ePHI:

(i) The terms of the consent under Section 10.2, Individual Consent, and the terms of the Privacy and Security Notice under Section 10.3.1, which sets forth requirements that apply to the Privacy and Security Notice;

(ii) Section 10.3.2, which requires Signatory to collect the Individual's written consent with respect to any material change in the applicable Privacy and Security Notice;

(iii) Section 10.4, Individual Rights; and

(iv) Section 10.5, Additional Security Requirements for IAS Providers.

10.6.2 Section 10.5.3, TEFCA Security Incident Notice to Affected Individuals, shall survive for a period of six (6) years following the expiration or termination of the applicable Framework Agreement.

10.7 Provisions that Apply to Subcontractors and Agents of IAS Providers **(Required Flow-Down).** To the extent that Signatory is an IAS Provider and uses subcontractors or agents with respect to the provision of such Individual Access Services, it shall

include in a written agreement with each such subcontractor or agent a requirement to comply with the following:

(i) To act in accordance with each of the applicable consents required of Signatory under Section 10.2;

(ii) To act in accordance with each of Signatory's applicable Written Privacy and Security Notices pursuant to Section 10.3;

(iii) To act in accordance with Section 10.4 when directed to do so by Signatory;

(iv) With respect to the information for which the subcontractor or agent provides services to Signatory in its role as an IAS Provider, the agent or subcontractor shall implement the applicable security requirements set forth in this Common Agreement (other than Sections 12.1.5, 12.1.6 and 12.3) and the security SOPs for **all** such Individually Identifiable information, regardless of whether such information is TI, to the same extent as they apply to Signatory; provided, however, that for purposes of the Flow-Down Provisions of this Section 10.7, if the IAS Provider is a Participant or Subparticipant, only Sections 12.1.4 and 12.2 shall apply;

(v) To encrypt **all** Individually Identifiable information both in transit and at rest, regardless of whether such data are TI pursuant to Section 10.5.2; and

(vi) To notify Signatory that is an IAS Provider for which it provides services with respect to each Individual whose TI has been or is reasonably believed to have been affected by a TEFCA Security Incident involving the subcontractor or agent in the manner and within the timeframe specified pursuant to Section 10.5.3.

Each agreement between Signatory and a subcontractor or agent with respect to the provision of Individual Access Services shall also provide that subsections (i) through (v) above shall continue in effect after termination or expiration of such agreement at least until expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual to whom the information relates. Each such agreement shall also provide that subsection (vi) above shall survive for at least six (6) years following the termination or expiration of such agreement.

11. Privacy

11.1 Compliance with the HIPAA Privacy Rule **(Required Flow-Down)**. If Signatory is a NHE (but not to the extent that it is acting as an entity entitled to make a Government Benefits Determination under Applicable Law, a Public Health Authority, or a Government Health Care Entity), then it shall comply with the provisions of the HIPAA Privacy Rule listed below with respect to all Individually Identifiable information that Signatory reasonably believes is TI as if such information is Protected Health Information and Signatory is a Covered Entity. Such compliance shall be consistent with Section 13.2 (Compliance with Specific Obligations) and enforced as part of its obligations pursuant to this Common Agreement.

11.1.1 From 45 CFR § 164.502, General Rules **(Required Flow-Down)**:

- Subsection (a)(1) – Dealing with permitted Uses and Disclosures, **but only to the extent Signatory is authorized to engage in the activities described in this subsection of the HIPAA Privacy Rule for the applicable Exchange Purpose.**
- Subsection (a)(2)(i) – Requiring Disclosures to Individuals
- Subsection (a)(3) – Business Associates
- Subsection (a)(5) – Dealing with prohibited Uses and Disclosures
- Subsection (b) – Dealing with the Minimum Necessary standard
- Subsection (c) – Dealing with agreed-upon restrictions
- Subsection (d) – Dealing with deidentification and re-identification of information
- Subsection (e) – Dealing with Business Associate contracts
- Subsection (f) – Dealing with deceased persons' information
- Subsection (g) – Dealing with personal representatives
- Subsection (h) – Dealing with confidential communications
- Subsection (i) – Dealing with Uses and Disclosures consistent with notice
- Subsection (j) – Dealing with Disclosures by whistleblowers

11.1.2 45 CFR § 164.504, Organizational Requirements **(Required Flow-Down)**.

11.1.3 45 CFR § 164.508, Authorization Required **(Required Flow-Down)**. Notwithstanding the foregoing, the provisions of Sections 10.2 and 10.3 shall

control and this Section 11.1.3 shall not apply with respect to an IAS Provider that is a NHE.

11.1.4 45 CFR § 164.510, Uses and Disclosures Requiring Opportunity to Agree or Object **(Required Flow-Down)**. Notwithstanding the foregoing, an IAS Provider that is a NHE but is not a Health Care Provider shall not have the right to make the permissive Disclosures described in § 164.510(3) - Emergency circumstances; provided, however, that an IAS Provider is not prohibited from making such a Disclosure if the Individual has consented to the Disclosure pursuant to Section 10 of this Common Agreement.

11.1.5 45 CFR § 164.512, Authorization or Opportunity to Object Not Required **(Required Flow-Down)**. Notwithstanding the foregoing, an IAS Provider that is a NHE but is not a Health Care Provider shall not have the right to make the permissive Disclosures described in § 164.512(c) - Standard: Disclosures about victims of abuse, neglect or domestic violence; § 164.512 Subsection (d) - Standard: Uses and disclosures for health oversight activities; and § 164.512 Subsection (j) - Standard: Uses and disclosures to avert a serious threat to health or safety; provided, however, that an IAS Provider is not prohibited from making such a Disclosure(s) if the Individual has consented to the Disclosure(s) pursuant to Section 10 of this Common Agreement.

11.1.6 From 45 CFR § 164.514, Other Requirements Relating to Uses and Disclosures **(Required Flow-Down)**:

- Subsections (a)-(c) – Dealing with de-identification requirements that render information **not** Individually Identifiable for purposes of this Section 11 and TEFCA Security Incidents
- Subsection (d) – Dealing with Minimum Necessary requirements
- Subsection (e) – Dealing with Limited Data Sets

11.1.7 45 CFR § 164.522, Rights to Request Privacy Protections **(Required Flow-Down)**.

11.1.8 45 CFR § 164.524, Access of Individuals **(Required Flow-Down)**, except that an IAS Provider that is a NHE shall be subject to the requirements of Section 10 with respect to access by Individuals for purposes of Individual Access Services and not this Section 11.1.8.

11.1.9 45 CFR § 164.528, Accounting of Disclosures **(Required Flow-Down)**.

11.1.10 From 45 CFR § 164.530, Administrative Requirements **(Required Flow-Down)**:

- Subsection (a) – Dealing with personnel designations
- Subsection (b) – Dealing with training
- Subsection (c) – Dealing with safeguards
- Subsection (d) – Dealing with complaints
- Subsection (e) – Dealing with sanctions
- Subsection (f) – Dealing with mitigation
- Subsection (g) – Dealing with refraining from intimidating or retaliatory acts
- Subsection (h) – Dealing with waiver of rights
- Subsection (i) – Dealing with policies and procedures
- Subsection (j) – Dealing with documentation

11.2 Written Privacy Policy **(Required Flow-Down)**. Signatory must develop, implement, make publicly available, and act in accordance with a written privacy policy describing its privacy practices with respect to Individually Identifiable information that is Used or Disclosed pursuant to this Common Agreement. Signatory can satisfy the written privacy policy requirement by including applicable content consistent with the HIPAA Rules into its existing privacy policy, except as otherwise stated herein with respect to IAS Providers. This written privacy policy requirement does not supplant the HIPAA Privacy Rule obligations of a QHIN, Participant, or a Subparticipant that is a Covered Entity to post and distribute a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520. If Signatory is a Covered Entity, then this written privacy practices requirement can be satisfied by its Notice of Privacy Practices. If Signatory is an IAS Provider, then the written privacy practices requirement **must** be in the form of a Privacy and Security Notice that meets the requirements of Section 10.3 of this Common Agreement.

12. Security

12.1 General Security Requirements. Signatory shall comply with the HIPAA Security Rule as if the HIPAA Security Rule applied to Individually Identifiable information that is TI regardless of whether Signatory is a Covered Entity or a Business Associate. Signatory shall also comply with the security requirements stated in Section 12 of this Common Agreement and specific additional requirements as described in the

QTF and applicable SOPs, to the extent that such requirements are not already included in the HIPAA Security Rule, with respect to all Individually Identifiable information that is TI as if such information were Protected Health Information and Signatory were a Covered Entity or Business Associate. Notwithstanding anything else in this Section 12, none of these requirements shall apply to any federal agency or Public Health Authority.

12.1.1 Cybersecurity Coverage. In accordance with the Cybersecurity Coverage SOP, Signatory shall maintain, throughout the term of this Common Agreement: (i) a policy or policies of insurance for cyber risk and technology errors and omissions; (ii) internal financial reserves to self-insure against a cyber-incident; or (iii) some combination of (i) and (ii).

12.1.2 Cybersecurity Certification. Signatory shall achieve and maintain third-party certification to an industry-recognized cybersecurity framework demonstrating compliance with all relevant security controls, as set forth in the applicable SOP.

12.1.3 Annual Security Assessments. Signatory must obtain a third-party security assessment and technical audit no less often than annually and as further described in the applicable SOP. Signatory must also provide evidence of compliance with this section and, if applicable, of appropriate mitigation efforts in response to the findings of the security assessment and/or technical audit within thirty (30) days to the RCE as specified in the SOP.

12.1.4 Participants and Subparticipants **(Required Flow-Down)**. Signatory shall require in its Participant-QHIN Agreements that its Participants implement and maintain, and require their Subparticipants to implement and maintain, appropriate security controls for TI that are commensurate with risks to the confidentiality, integrity, and/or availability of the TI. If any Participant or Subparticipant is a NHE, it shall be required to comply with the HIPAA Security Rule provisions with respect to all Individually Identifiable information that the Participant or Subparticipant reasonably believes is TI as if such information were Protected Health Information and the Participant or Subparticipant were a Covered Entity or Business Associate. Signatory shall further require that its Participants implement and maintain, and that its Participants require their Subparticipants to implement and maintain, any additional security requirements that may be set forth in an SOP applicable to Participants and Subparticipants. Such compliance shall be enforced as part of the Participants' and Subparticipants' obligations pursuant to the Framework Agreements.

12.1.5 Security Resource Support to Participants. Signatory shall make available to its Participants: (i) security resources and guidance regarding the protection of TI applicable to the Participants' participation in the QHIN under the applicable Framework Agreement; and (ii) information and resources that the RCE or Security Council makes available to Signatory related to promotion and enhancement of the security of TI under the Framework Agreements.

12.1.6 Chief Information Security Officer. The RCE shall designate a person to serve as the Chief Information Security Officer (CISO) for activities conducted under the Framework Agreements. This may be either an employee or independent contractor of the RCE. The RCE's CISO will be responsible for monitoring and maintaining the overall security posture of activities conducted under the Framework Agreements and making recommendations to all QHINs regarding changes to baseline security practices required to address changes to the threat landscape. Signatory agrees that it, and not the RCE, is ultimately responsible for the security posture of Signatory's network and the activities conducted by Signatory under the Participant-QHIN Agreements to which Signatory is a party, as well as the Participant-Subparticipant Agreements its Participants enter into and all Downstream Subparticipant Agreements that its Participants' Subparticipants enter into. Signatory shall also designate a person to serve as its CISO for purposes of Signatory's participation in QHIN-to-QHIN exchange. The RCE shall establish a Cybersecurity Council to enhance cybersecurity commensurate with the risks of the activities conducted under the Framework Agreements as more fully set forth in an SOP.

12.2 TI Outside the United States **(Required Flow-Down)**. Signatory shall not Use TI outside the United States or Disclose TI to any person or entity outside the United States except to the extent such Use or Disclosure is permitted or required by Applicable Law and except to the extent the Use or Disclosure is conducted in conformance with the HIPAA Security Rule, regardless of whether Signatory is a Covered Entity or Business Associate. Signatory shall evaluate the risks of any extraterritorial Uses and/or Disclosures of TI, if applicable, as part of an annual security assessment and prior to any new or substantially different type of non-U.S. Use(s) or Disclosure(s). Such security assessment shall include a risk assessment to evaluate whether the Uses or Disclosures of Individually Identifiable information that is reasonably believed to be TI by or to persons or entities outside the United States satisfies the requirements of the HIPAA Security Rule. The foregoing does not modify or eliminate any provision of Applicable Law that does not permit a Signatory

to Disclose Individually Identifiable information to a person or entity outside the United States or that imposes conditions or limitations on such Disclosure.

12.3 TEFCA Security Incident Notification. As soon as reasonably practicable, but not more than five (5) calendar days after determining that an TEFCA Security Incident has occurred, Signatory shall provide notification to the RCE and to all QHINs that are likely impacted, whether directly or by nature of one of the other QHIN's Participants or Subparticipants, of the TEFCA Security Incident. Such notification must include sufficient information for the RCE and others affected to understand the nature and likely scope of the TEFCA Security Incident. Signatory shall supplement the information contained in the notification as it becomes available and cooperate with the RCE, and with other QHINs, Participants, and Subparticipants that are likely impacted by the TEFCA Security Incident.

12.3.1 Receiving TEFCA Security Incident Notification. Signatory shall implement a reporting protocol by which other QHINs can provide Signatory with notification of a TEFCA Security Incident. In the event that the TEFCA Security Incident involves TI that is de-identified in accordance with the de-identification standard provided at 45 CFR § 164.514(a), then no such reporting obligation shall exist.

12.3.2 Vertical Reporting of TEFCA Security Incident(s). Signatory shall require that each Participant with which it has entered into a Participant-QHIN Agreement:

(i) Notify Signatory and Participant's Subparticipants of any TEFCA Security Incident the Participant experiences in accordance with the timing and content requirements stated in Section 12.3;

(ii) Require that each Subparticipant with which the Participant enters into a Participant-Subparticipant Agreement report any TEFCA Security Incident experienced by or reported to the Subparticipant to the Participant and to the Subparticipant's Downstream Subparticipants in accordance with the timing and content requirements stated in Section 12.3;

(iii) Require that each Subparticipant with which the Participant enters into a Participant-Subparticipant Agreement require that its Downstream Subparticipants report any TEFCA Security Incident experienced by or reported to the Downstream Subparticipant to the Upstream Subparticipant and to its own

Downstream Subparticipants, in accordance with the timing and content requirements stated in Section 12.3.

(iv) Notify Signatory of any TEFCA Security Incident reported to the Participant by one of its Subparticipants.

12.3.3 Compliance with Notification Under Applicable Law. Nothing in this Section 12.3 shall be deemed to modify or replace any breach notification requirements that Signatory may have under the HIPAA Rules, the FTC Rule, and/or other Applicable Law. To the extent Signatory is already required by Applicable Law to notify a Participant, Subparticipant, and/or another QHIN of an incident that would also be a TEFCA Security Incident, this section does not require duplicative notification.

13. General Obligations

13.1 Compliance with Applicable Law and the Framework Agreements **(Required Flow-Down)**. Signatory shall comply with all Applicable Law and shall implement and act in accordance with any provision required by this Common Agreement, including all applicable SOPs and provisions of the QTF.

13.2 Compliance with Specific Obligations.

13.2.1 Responsibility of the RCE. The RCE shall be responsible for taking reasonable steps to confirm that Signatory is abiding by the obligations under this Common Agreement and all applicable SOPs. In the event that the RCE becomes aware of a material non-compliance with any of the obligations stated in the Common Agreement or any of the applicable SOPs by Signatory, then the RCE shall promptly notify Signatory in writing. Such notice shall inform Signatory that its failure to correct any such deficiencies within the timeframe established by the RCE shall constitute a material breach of this Common Agreement, which may result in termination of this Common Agreement.

13.2.2 Responsibility of Signatory **(Required Flow-Down)**. Signatory shall be responsible for taking reasonable steps to confirm that all of its Participants are abiding by the Required Flow-Downs and all applicable SOPs. In the event that Signatory becomes aware of a material non-compliance by one of its Participants, then Signatory shall promptly notify the Participant in writing. Such notice shall inform the Participant that its failure to correct any

such deficiencies within the timeframe established by Signatory shall constitute a material breach of the Participant-QHIN Agreement, which may result in early termination of said agreement.

13.3 Flow-Down Rights to Suspend **(Required Flow-Downs)**.

13.3.1 Suspension Rights Granted to RCE. Each Participant-QHIN Agreement, Participant-Subparticipant Agreement, and Downstream Subparticipant Agreement shall include a grant of authority to the RCE to suspend each party's right to engage in any QHIN-to-QHIN exchange activities if: (i) there is an alleged violation of such agreement or of Applicable Law by the party/parties; (ii) there is a cognizable threat to the security of the information that the RCE reasonably believes is TI transmitted pursuant to such agreement or to the infrastructure of the QHIN; or (iii) such suspension is in the interests of national security as directed by an agency of the United States government.

13.3.2 Suspension Rights Granted to Signatory. Each of the aforementioned Framework Agreements shall also grant Signatory the same authority as the RCE to suspend a party's right to engage in any activities under the Framework Agreement if any of the circumstances described in subsections 13.3.1 (i)-(iii) above occur with respect to any Participant and/or Subparticipant of Signatory.

(i) Signatory *may* exercise such right to suspend based on its own determination that any of the circumstances described in subsections 13.3.1 (i)-(iii) above occurred with respect to any Participant and/or Subparticipant of Signatory.

(ii) Signatory ***must*** exercise such right to suspend if directed to do so by the RCE based on the RCE's determination that suspension is warranted based on any of the circumstances described in subsections 13.3.1 (i)-(iii) above with respect to any Participant and/or Subparticipant of Signatory. If the suspension of any Participant and/or Subparticipant of Signatory is at the direction of the RCE, Signatory must effectuate such suspension as soon as practicable and not longer than within twenty-four (24) hours of the RCE having directed the suspension, unless the RCE specifies a longer period of time is permitted to effectuate the suspension.

13.4 Survival for Participants and Subparticipants (**Required Flow-Downs**). The following are the minimum survival provisions and respective minimum time periods that shall be included in each of the Framework Agreements other than this Common Agreement. Signatory shall include at least the following survival provisions in all of its Participant-QHIN Agreements and shall require its Participants to include the following minimum survival provisions and minimum survival time periods in all their Participant-Subparticipant Agreements as Required Flow-Downs so that such provisions will also be included as minimum survival provisions and minimum survival time periods in all Downstream Subparticipant Agreements.

13.4.1 Section 7.1, Confidential Information, shall survive for a period of six (6) years following the expiration or termination of the applicable Framework Agreement.

13.4.2 Section 10.6, Survival for IAS Providers, to the extent that the Participant or Subparticipant is an IAS Provider, shall survive following the expiration or termination of the applicable Framework Agreement for the respective time periods set forth in Section 10.6.

13.4.3 Section 11, Privacy, to the extent that the Participant or Subparticipant is subject to Section 11, said Section shall survive the expiration or termination of the applicable Framework Agreement until the expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under Subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual to whom the information covered by Section 11 relates.

13.4.4 Section 12.1.4, Participants and Subparticipants, to the extent that the Participant or Subparticipant is subject to Section 12.1.4, said Section shall survive the expiration or termination of the applicable Framework Agreement until the expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under Subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual to whom the information covered by Section 12.1.4 relates.

13.4.5 The requirements of Section 12.3.2, Vertical Reporting of TEFCA Security Incident(s), shall survive for a period of six (6) years following the expiration or termination of the applicable Framework Agreement.

14. Specific QHIN Obligations

14.1 Transparency – Access to Participant-QHIN Information. If either ONC or the RCE has a reasonable basis to believe that one or more of the following situations exist with respect to Signatory, then Signatory shall make available, upon written request, copies of its Participant-QHIN Agreements and information relating to the exchange of TI and the circumstances giving rise to the basis for such request. The foregoing shall be subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges but only to the extent that such information is material to the defense of a substantiated claim asserted by a third party. Such situations include: (i) an alleged violation of this Common Agreement or Applicable Law; or (ii) a threat to the security of information that the RCE or ONC reasonably believes is TI transmitted pursuant to the Framework Agreements or to the infrastructure supporting QHIN-to-QHIN exchange. The right of Signatory to restrict or condition its cooperation or disclosure of its Participant-QHIN Agreement(s) and information relating to the exchange of TI in the interest of preserving privileges shall not apply to a disclosure that is requested in the interest of national security.

14.2 Compliance with Standard Operating Procedures. The RCE shall adopt Standard Operating Procedures (SOPs) to provide detailed guidance on specific aspects of the exchange activities under this Common Agreement that are binding on the RCE, Signatory and, as applicable, Participants and Subparticipants. The SOPs are incorporated by reference into this Common Agreement, and Signatory shall comply with all SOPs that are applicable to it and shall require that its Participants and their Subparticipants agree in writing to comply with all applicable SOPs. If Signatory or its Participants or Subparticipants fail to comply with any applicable SOP, the RCE may take corrective action, which will include requiring steps to bring the organization into compliance with the SOP and may include requiring Signatory to suspend the ability of a Participant or Subparticipant to exchange information under the Framework Agreement(s) until the non-compliance is corrected to the satisfaction of the RCE, suspending Signatory's right to exchange information under the Common Agreement or Signatory may have its right to exchange information under the Common Agreement terminated or be required to ensure the termination of its Participant's or a Subparticipant's right to exchange information under one of the other Framework Agreements. RCE shall adopt an SOP that provides detailed information about sanctions for non-compliance with an SOP. Nothing in this Section 14.2 of this Common Agreement limits the RCE's rights to terminate this Common Agreement under Section 16.3.2 or 16.3.3 of this Common Agreement.

14.3 Incorporation of Required Flow-Downs in Framework Agreements. In addition to the obligations of Signatory with respect to its Participants stated throughout in this Common Agreement:

(i) Signatory shall be responsible for incorporating the Required Flow-Downs into all Participant-QHIN Agreements.

(ii) Signatory shall require that each of its Participants be responsible for incorporating the Required Flow-Downs into all Participant-Subparticipant Agreements.

(iii) Signatory shall further require that each of its Participants be responsible for requiring that each of their Subparticipants incorporate the Required Flow-Downs into all Downstream Subparticipant Agreements, if any.

14.4 Compliance with the QHIN Technical Framework. Signatory shall meet the requirements of the then-applicable QTF. Signatory is required to comply with any updates to the QTF by the applicable date established by the RCE and approved by ONC.

15. Dispute Resolution

15.1 Acknowledgement and Consent to Dispute Resolution Process. Signatory acknowledges that it may be in its best interest to resolve Disputes related to the Common Agreement through a collaborative, collegial process rather than through civil litigation. Signatory has reached this conclusion based upon the fact that the legal and factual issues related to the exchange and related activities under the Common Agreement are unique, novel, and complex, and limited case law exists that addresses the legal issues that could arise in connection with this Common Agreement. Therefore, Signatory shall submit Disputes to the RCE to be addressed by the non-binding Dispute resolution process set forth in an SOP (the "Dispute Resolution Process"). Notwithstanding, Signatory understands that the Dispute Resolution Process does not supersede or replace any oversight, investigatory, enforcement, or other administrative actions or processes that may be taken by the relevant authority, whether or not arising out of or related to the circumstances giving rise to the Dispute. RCE and Signatory are committed to promptly and fairly resolving Disputes.

To that end, Signatory shall use its best efforts to resolve Disputes that may arise with other QHINs, their respective Participants, or the RCE through informal

discussions before seeking to invoke the Dispute Resolution Process. If the Dispute cannot be resolved through cooperation between Signatory and the other QHIN(s), Signatory may, on its own behalf or on behalf of its Participant(s), choose to submit the Dispute to the Dispute Resolution Process. Likewise, Signatory, on its own behalf and on behalf of its Participant(s), will seek to resolve Disputes involving the RCE through good-faith informal discussions with the RCE prior to invoking the Dispute Resolution Process.

Under no circumstances will the Dispute Resolution Process give the RCE any power to assess monetary damages against any party to the Dispute Resolution Process including, without limitation, Signatory or its Participants or any other QHIN or its Participants. Except in accordance with Section 15.2, if Signatory refuses to participate in the Dispute Resolution Process, such refusal shall constitute a material breach of this Common Agreement and may be grounds for termination of Signatory's participation in QHIN-to-QHIN exchange.

15.2 Injunctive Relief.

15.2.1 Notwithstanding Section 15.1, Signatory shall be relieved of its obligation to participate in the Dispute Resolution Process if Signatory: (i) makes a good faith determination that is based upon available information or other evidence that another QHIN's or its Participants' acts or omissions will cause irreparable harm to Signatory or another organization or person (e.g., another QHIN or its Participant or an Individual); and (ii) pursues immediate injunctive relief against such QHIN or its Participant in a court of competent jurisdiction in accordance with Section 18.3. Signatory must inform RCE of such action within two (2) business days of filing for the injunctive relief and of the result of the action within twenty-four (24) hours of a court of competent jurisdiction granting or denying injunctive relief.

15.2.2 If the injunctive relief sought in Section 15.2.1 is not granted and Signatory chooses to pursue the Dispute, the Dispute must be submitted to the Dispute Resolution Process in accordance with Section 15.1.

15.3 Activities during Dispute Resolution Process. The pendency of a Dispute under this Common Agreement has no effect on either Party's obligations hereunder, unless Signatory terminates its rights in accordance with Section 16.2 or 16.3.1 or is suspended in accordance with Section 16.4.2.

15.4 Implementation of Agreed Upon Resolution. If, at any point during the Dispute Resolution Process, Signatory and all other parties to the Dispute accept a proposed

resolution of the Dispute, Signatory and RCE each agree to implement the terms of the resolution within the agreed-upon timeframe to the extent applicable to each of them.

15.5 Reservation of Rights. If, following the completion of the Dispute Resolution Process, in the opinion of Signatory, the Dispute Resolution Process failed to adequately resolve the Dispute, Signatory may pursue any remedies available to it in a court of competent jurisdiction in accordance with Section 18.3.

15.6 Escalation and Reporting of Disputes to ONC.

15.6.1 Escalation of Certain Disputes to ONC. If Signatory has reason to believe that: (i) the RCE is acting in a discriminatory manner or in violation of the RCE's conflict of interest policies; or (ii) the RCE has not acted in accordance with its obligations stated in this Common Agreement, then Signatory shall have the right, on its own behalf and on behalf of its Participants, to make a complaint to ONC. The complaint shall identify the parties to the Dispute, a description of the Dispute, a summary of each party's position on the issues included in the Dispute, the final disposition of the Dispute, and the basis for the RCE's alleged misconduct. The RCE and Signatory shall each also promptly provide such additional information as may be reasonably requested by ONC in order to consider and resolve the issues raised for review. Since this complaint may include PHI and may include Confidential Information, the RCE will work with ONC to develop mechanisms to protect the confidentiality of this information. Such protective mechanisms and the process for escalating a complaint to ONC are set forth in an SOP.

15.6.2 Reporting of Anonymized Dispute Information to ONC. As part of the RCE's communications with ONC, within fifteen (15) business days after the end of each calendar quarter, the RCE reports the following information relating to each Dispute that has been submitted through the Dispute Resolution Process in an anonymized format to ONC: (i) identification of whether the parties to the Dispute are QHIN(s) only, or whether the Dispute also involves Participant(s); (ii) a description of the Dispute with reasonable specificity; and (iii) the final disposition of the Dispute.

16. Stability of the QHIN Network

16.1 Term. This Common Agreement shall commence on the Effective Date and shall remain in effect until it is terminated by either Party in accordance with the terms of this Common Agreement.

16.2 Withdrawal and Termination Prior to QHIN Designation.

16.2.1 By Signatory. Signatory may withdraw from Onboarding and terminate this Common Agreement at any time before it is Designated if it determines that it cannot meet the requirements of being a QHIN or if it chooses not to continue to seek status as a QHIN. Signatory must provide at least fifteen (15) calendar days' written notice to RCE of its intention to withdraw from Onboarding and terminate this Common Agreement.

16.2.2 By the RCE. If Signatory fails to complete the Onboarding requirements within the timeframe specified in the Onboarding & Designation SOP, the RCE may withdraw Signatory from Onboarding and terminate this Common Agreement upon fifteen (15) calendar days' written notice to Signatory that Signatory has failed to meet the Onboarding requirements and, therefore, cannot be Designated. The foregoing shall not be interpreted as precluding Signatory from reapplying for Designation at a future time.

16.3 Termination.

16.3.1 Termination by Signatory. Signatory may terminate this Common Agreement at any time without cause by providing ninety (90) days' prior written notice to RCE. Signatory may also terminate for cause if the RCE commits a material breach of the Common Agreement, and the RCE fails to cure its material breach within thirty (30) days of Signatory providing written notice to RCE of the material breach; provided, however, that if RCE is diligently working to cure its material breach at the end of this thirty- (30-) day period, then Signatory must provide the RCE with up to another thirty (30) days to complete its cure.

16.3.2 Termination by the RCE. RCE may not terminate this Common Agreement without cause as described in this Section 16.3.2 or Section 16.3.3 of this Common Agreement. RCE may terminate this Common Agreement with immediate effect by giving notice to Signatory if: (i) Signatory is in material breach of any of the terms and conditions of this Common Agreement and fails to remedy such breach within thirty (30) days after receiving notice of

such breach; provided, however, that if Signatory is diligently working to cure its material breach at the end of this thirty- (30-) day period, then RCE must provide Signatory with up to another thirty (30) days to complete its cure; or (ii) Signatory breaches a material provision of this Common Agreement where such breach is not capable of remedy.

16.3.3 Termination by RCE if the RCE Ceases to be Funded. The Parties acknowledge that the RCE's activities under this Common Agreement are supported by ONC funding. If this funding ceases, there are no guarantees that the RCE will continue unless a financial sustainability model has been put in place. If federal funding ceases, or if the available funding is not sufficient to provide the necessary funding to support operation of the RCE and there is no successor RCE, then the RCE may terminate this Common Agreement by providing one hundred and eighty (180) days' prior written notice to Signatory.

16.3.4 Termination by Mutual Agreement. The Parties may terminate this Common Agreement at any time and for any reason by mutual, written agreement.

16.3.5 Effect of Termination of the Common Agreement.

(i) Upon termination of this Common Agreement for any reason, RCE shall promptly remove Signatory and its Participants and Subparticipants from the RCE Directory Service and any other lists of QHINs that RCE maintains.

(ii) Upon termination of this Common Agreement for any reason, Signatory shall, without undue delay, (a) remove all references that identify it as a QHIN from all media, and (b) cease all use of any material, including but not limited to product manuals, marketing literature, and web content that identifies it as a QHIN. Within twenty (20) business days of termination of this Common Agreement, Signatory shall confirm to RCE, in writing, that it has complied with this Subsection.

(iii) To the extent Signatory stores TI, such TI may not be distinguishable from other information maintained by Signatory. When the TI is not distinguishable from other information, it is not possible for Signatory to return or destroy TI it maintains upon termination or expiration of this Common Agreement. Upon termination or expiration of this Common Agreement, if Signatory

is subject to Section 11 of this Common Agreement, such sections shall continue to apply so long as the information would be ePHI if maintained by a Covered Entity or Business Associate. The protections required under the HIPAA Security Rule shall also continue to apply to all TI that is ePHI, regardless of whether Signatory is a Covered Entity or Business Associate.

(iv) In no event shall Signatory be entitled to any refund of any fees that it has paid the RCE prior to termination.

16.4 Suspension.

16.4.1 Suspension by RCE. RCE may suspend Signatory's ability to engage in exchange activities under the Common Agreement if RCE determines, following completion of a preliminary investigation, that Signatory is responsible for a Threat Condition. To the extent that RCE determines that one of Signatory's Participants or Subparticipants has done something or failed to do something that results in a Threat Condition, RCE may suspend, or the RCE may direct that Signatory suspend, that Participant's or Subparticipant's ability to engage in exchange activities under the Common Agreement. RCE will make a reasonable effort to notify Signatory in advance of RCE's intent to suspend Signatory or one of Signatory's Participants or Subparticipants, including notice of the Threat Condition giving rise to such suspension. If advance notice is not reasonably practicable under the circumstances, the RCE will notify Signatory of the suspension, and the Threat Condition giving rise thereto, as soon as practicable following the suspension. Upon suspension of either Signatory or one of Signatory's Participants or Subparticipants, RCE will work collaboratively with Signatory to resolve the issue leading to the suspension. RCE shall adopt an SOP to address specific requirements and timelines related to suspension.

16.4.2 Selective Suspension by Signatory. Signatory may, in good faith and to the extent permitted by Applicable Law, determine that it must suspend exchanging with another QHIN with which it is otherwise required to exchange in accordance with an SOP because of reasonable and legitimate concerns related to the privacy and security of information that is exchanged. If Signatory makes this determination, it is required to promptly notify the RCE and the QHIN that Signatory is suspending of its decision and the reason(s) for making the decision. If Signatory makes the decision to suspend, it is required, within thirty (30) days, to initiate the Dispute Resolution Process in order to resolve whatever issues led to the decision to

suspend, or end its suspension and resume exchanging with the other QHIN. Provided that Signatory selectively suspends exchanging with another QHIN in accordance with this Section and in accordance with Applicable Law, such selective suspension shall not be deemed a violation of Section 6.2.2.

16.4.3 Additional Suspension Rights of RCE. Notwithstanding anything to the contrary set forth herein, the RCE retains the right to suspend any exchange activity under the Common Agreement (i) upon ten (10) days' prior notice if the RCE determines that Signatory has created a situation in which the RCE may suffer material harm and suspension is the only reasonable step that the RCE can take to protect itself; or (ii) immediately if the RCE determines that the safety or security of any person or the privacy or security of TI and/or Confidential Information is threatened. In the case of an immediate suspension under this section, the RCE will provide notice as soon as practicable following the suspension.

16.4.4 Effect of Suspension. The suspension of Signatory's ability to participate in any activity under this Common Agreement pursuant to this section has no effect on Signatory's other obligations hereunder, including, without limitation, obligations with respect to privacy and security. During any suspension pursuant to this section, Signatory's inability to exchange information under this Common Agreement or comply with those terms of this Common Agreement that require information exchange shall not be deemed a breach of this Common Agreement. In the event of suspension of Signatory's ability to participate in exchange activities under this Common Agreement, Signatory shall communicate to its Participants, and require that they communicate to their Subparticipants, that all QHIN-to-QHIN exchange on behalf of Signatory's Participants and Subparticipants will also be suspended during any period of Signatory's suspension.

16.5 Successor RCE and Transition.

16.5.1 Selection of RCE and Successor RCE(s) and Continuing Obligations. Signatory agrees that ONC had the right to select the initial RCE and that ONC shall have the right to select any successor RCE and/or to act as an interim RCE until such successor RCE has been selected. Signatory further agrees to work cooperatively with the RCE and any interim or successor RCE selected by ONC in accordance with this Common Agreement. Additionally, Signatory shall continue to abide by the provisions of this Common Agreement during the transition to any interim or successor RCE.

16.5.2 RCE Transition Services. In the event that ONC selects a successor RCE, the then-current RCE will be required to continue supporting functions throughout a ninety- (90-) day closeout period. If ONC acts as an interim RCE prior to the appointment of a successor RCE, the references to successor RCE shall apply to ONC as the interim RCE.

17. Fees

17.1 Fees Paid by QHINs to the RCE. Signatory shall pay the fees set forth on Schedule 1 attached hereto (the "QHIN Fees"). RCE shall invoice Signatory for all Fees in accordance with Schedule 1. Unless otherwise set forth in Schedule 1, invoices shall be due and payable by Signatory within sixty (60) days after receipt thereof unless Signatory notifies RCE in writing that it is contesting the accuracy of the invoice and identifies the specific inaccuracies that it asserts. QHIN Fees contested under this Section shall be resolved between Signatory and RCE as stated in the applicable SOP. Other than with regard to invoiced amounts that are contested in good faith, any collection costs, attorneys' fees or other expenses reasonably incurred by RCE in collecting amounts due under this Common Agreement are the responsibility of Signatory. If Signatory fails to pay any undisputed QHIN Fees when due hereunder, RCE has the right to suspend Signatory's ability to participate in any exchange activity under this Common Agreement. Prior to taking any action against Signatory for non-payment, including suspension, RCE shall provide Signatory ten (10) days' prior written notice. If Signatory makes payment within ten (10) days of receiving written notice, RCE will not suspend Signatory's ability to participate in any exchange activity under this Common Agreement. If Signatory fails to make payment within ten (10) days of receiving notice, then the RCE may implement the suspension or may terminate Signatory's ability to participate in any exchange activity under this Common Agreement.

17.1.1 Changes to QHIN Fees. Schedule 1 may be updated by the RCE from time-to-time in relation to operational costs, availability of ONC funding, and other market factors in order to ensure the sustainability of the activities conducted under the Framework Agreements. In light of the foregoing, changes to Schedule 1 are not subject to the change management process set forth in Section 5. The RCE shall provide Signatory not less than ninety (90) days' advance written notice of any adjustments to the QHIN Fees set forth in Schedule 1.

17.2 Fees Paid by QHINs to Other QHINs. Signatory is prohibited from charging fees to other QHINs for any exchange of information using the Connectivity Services.

18. Contract Administration

18.1 Authority to Execute. Signatory warrants and represents that it has the full power and authority to execute this Common Agreement and that any representative of Signatory who executes this Common Agreement has full power and authority to do so on behalf of Signatory.

18.2 Notices. All notices to be made under this Common Agreement shall be given in writing to Signatory and RCE at the addresses set forth following each Party's signature, and shall be deemed given: (i) upon delivery, if personally delivered; (ii) upon delivery by overnight delivery service such as UPS or FEDEX or another recognized commercial carrier; (iii) upon the date indicated on the return receipt, when sent by the United States Postal Service Certified Mail, return receipt requested; and (iv) if by facsimile telecommunication or other form of electronic transmission, upon receipt when the sending facsimile machine or electronic mail address receives confirmation of receipt by the receiving facsimile machine or electronic mail address.

SIGNATORY: _____

NOTICE TO:

Name/Title: _____

Address: _____

_____

_____

Facsimile: _____

E-mail: _____

THE SEQUOIA PROJECT, INC.

NOTICE TO:

Name/Title: _____

Address: _____

_____

_____

Facsimile: _____

E-mail: _____

18.3 Governing Law, Forum, and Jurisdiction.

18.3.1 Conflicts of Law and Governing Law. In the event of a Dispute between Signatory and the RCE, the applicable federal and state conflicts of law provisions that govern the operations of the Parties shall determine governing law.

18.3.2 Jurisdiction and Venue. The RCE, currently a Virginia non-profit corporation, and Signatory each hereby submits to the exclusive jurisdiction of any state or federal court sitting in the Commonwealth of Virginia within twenty-five (25) miles of Alexandria, Virginia in any legal proceeding arising out of or relating to this Common Agreement unless otherwise required by Applicable Law. The RCE and Signatory each agrees that all claims and matters arising out of this Common Agreement may be heard and determined in such court, and each Party hereby waives any right to object to such filing on grounds of improper venue, *forum non-conveniens*, or other venue-related grounds.

18.3.3 Federal Agency Forum Selection. In the event the RCE initiates a legal proceeding arising out of or relating to this Common Agreement *and* Signatory is a U.S. federal agency, the RCE shall initiate such proceeding in a federal court, in accordance with Section 18.3.2, unless the federal courts are without jurisdiction and this requirement would act to deprive the RCE of the ability to obtain a legal remedy. The foregoing shall not preclude the federal agency Signatory from challenging the jurisdiction of such state court.

18.3.4 Participant and Subparticipant Agreements. For the avoidance of doubt, Signatory's Participant-QHIN Agreements, and the Participant's Participant-Subparticipant Agreements, as well as any Downstream Subparticipant Agreements, shall be subject to the governing law, forum, and jurisdiction provisions of those agreements.

18.4 Assignment. None of this Common Agreement, including but not limited to any of the rights created by this Common Agreement, can be transferred by either Party, whether by assignment, merger, other operation of law, change of control of the Party or otherwise, without the prior written approval of the other Party. Notwithstanding the foregoing, if ONC selects another organization to serve as the RCE, then RCE shall assign this Common Agreement to the successor RCE or an interim RCE as directed by ONC. Signatory understands and agrees that no interim or successor RCE shall have any obligation or liability for any act or omission of The Sequoia Project in connection with this Common Agreement or any of the other Framework Agreements prior to the termination of The Sequoia Project's status as the RCE.

18.5 Force Majeure. Neither Party shall be responsible for any delays or failures in performance caused by the occurrence of events or other circumstances that are beyond its reasonable control after the exercise of commercially reasonable efforts to either prevent or mitigate the effect of any such occurrence or event.

18.6 Severability. If any provision of this Common Agreement shall be adjudged by any court of competent jurisdiction to be unenforceable or invalid, that provision shall be modified to the minimum extent necessary to achieve the purpose originally intended, if possible, and the remaining provisions of this Common Agreement shall remain in full force and effect and enforceable. If such provision cannot be modified to achieve the purpose originally intended, it shall be severed from the agreement and the remaining provisions of this Common Agreement shall remain in full force and effect and enforceable.

18.7 Counterparts. This Common Agreement may be executed in one or more counterparts, each of which shall be considered an original counterpart, and shall become a binding agreement when each Party shall have executed one counterpart.

18.8 Captions. Captions appearing in this Common Agreement are for convenience only and shall not be deemed to explain, limit, or amplify the provisions of this Common Agreement.

18.9 Independent Parties. Nothing contained in this Common Agreement shall be deemed or construed as creating a joint venture or partnership between Signatory and RCE.

18.10 Acts of Contractors and Agents. To the extent that the acts or omissions of a Party's agent(s) or contractor(s), or their subcontractor(s), result in that Party's breach of and liability under this Common Agreement, said breach shall be deemed to be a breach by that Party.

18.11 Entire Agreement; Waiver. This Common Agreement, together with the QTF, SOPs, and all other attachments, exhibits, and artifacts incorporated by reference, contains the entire understanding of the Parties with regard to the subject matter contained herein. The failure of either Party to enforce, at any time, any provision of this Common Agreement shall not be construed to be a waiver of such provision, nor shall it in any way affect the validity of this Common Agreement or any part hereof or the right of such Party thereafter to enforce each and every such provision. No waiver of any breach of this Common Agreement shall be held to constitute a waiver of any other or subsequent breach, nor shall any delay by either Party to exercise any right under this Common Agreement operate as a waiver of any such right.

18.12 Effect of Agreement. Except as provided in Sections 7.4 and Section 15, nothing in this Common Agreement shall be construed to restrict either Party's right to pursue all remedies available under law for damages or other relief arising from acts or omissions of RCE or other QHINs or their Participants or Subparticipants related to the Common Agreement, or to limit any rights, immunities, or defenses to which Signatory may be entitled under Applicable Law.

18.13 Priority. In the event of any conflict or inconsistency between Applicable Law, a provision of this Common Agreement, the QTF, an SOP, and/or any implementation plans, guidance documents, or other materials or documentation the RCE makes available to QHINs, Participants, and/or Subparticipants regarding the operations or activities conducted under the Framework Agreements, the following shall be the order of precedence for this Common Agreement to the extent of such conflict or inconsistency: (1) Applicable Law; (2) this document, including Required Flow-Downs that are to be incorporated into Framework Agreements; (3) the QTF; (4) the Dispute Resolution Process, as set forth herein and further detailed in an SOP; (5) all other SOPs; (6) all other attachments, exhibits, and artifacts incorporated herein by reference, and (7) other RCE plans, documents, or materials made available regarding activities conducted under the Framework Agreements.

18.14 QHIN Time Periods. Any of the time periods relating to the Parties hereto that are specified in this Common Agreement may be changed on a case-by-case basis pursuant to the mutual written consent of the Parties, provided that these changes are not undertaken to adversely affect another QHIN and provided that these changes would not unfairly benefit either Party to the detriment of others participating in activities under the Framework Agreements. Time periods that pertain to ONC may **not** be changed, except by ONC, including the time periods for ONC review of proposed changes to the Common Agreement, the QTF, or SOPs that are set forth in Section 5.

18.15 Remedies Cumulative. The rights and remedies of the Parties provided in this Common Agreement are cumulative and are in addition to any other rights and remedies provided by Applicable Law.

18.16 Survival of Rights and Obligations. The respective rights, obligations, and liabilities of the Parties with respect to acts or omissions that occur by either Party prior to the date of expiration or termination of this Common Agreement shall survive such expiration or termination. Following any expiration or termination of this Common Agreement, the Parties shall thereafter cooperate fully and work diligently in good faith to achieve an orderly resolution of all matters resulting from such expiration or termination.

18.16.1 The following sections shall survive expiration or termination of this Common Agreement as more specifically provided below:

(i) The following sections shall survive in perpetuity following the expiration or termination of this Common Agreement: Sections 7.4 Limitation of Liability; 18.2 Notices; 18.3 Governing Law, Forum and Jurisdiction; 18.6 Severability; 18.9 Independent Parties; 18.10 Acts of Contractors and Agents; 18.11 Entire Agreement; Waiver; 18.12 Effect of Agreement; 18.13 Priority; and 18.15 Remedies Cumulative.

(ii) The following sections shall survive for a period of six (6) years following the expiration or termination of this Common Agreement: Sections 7.1 Confidential Information; 7.2.1 Statement of General Principle; 12.3 TEFCA Security Incident Notification; and 14.1 Transparency - Access to Participant-QHIN Information.

(iii) The following section shall survive for the period specifically stated in such section following the expiration or termination of this Common Agreement: Section 16.3.5 Effect of Termination of Common Agreement.

(iv) To the extent that Signatory is an IAS Provider, the provisions set forth in Section 10.6 shall survive following the termination or expiration of this Common Agreement for the respective periods set forth therein.

IN WITNESS WHEREOF, the Parties hereto, intending legally to be bound hereby, have executed and delivered this Common Agreement as of the date first above written.

RCE: THE SEQUOIA PROJECT, INC.	**Signatory:** _____
_____	_____
Signature	Signature
By: _____	By: _____
Title: _____	Title: _____
Date: _____	Date: _____

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The Trusted Exchange Framework and Common Agreement are also available on the Office of the National Coordinator for Health Information Technology's public internet website at *www.HealthIT.gov/TEFCA.*

Authority: 42 U.S.C. 300jj–11.

Suhas Tripathi,

National Coordinator for Health Information Technology.

[FR Doc. 2022–00948 Filed 1–18–22; 8:45 am]

BILLING CODE 4150–45–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Support for Conferences and Scientific Meetings (R13).

Date: February 23, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karen Nieves-Lugo, M.P.H., Ph.D., Scientific Review Officer, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 480–4727, *karen.nieveslugo@nih.gov*.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Mentored Career and Research Development Awards (Ks).

Date: February 24–25, 2022.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Ave., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–1366, *ismonddr@mail.nih.gov*.

Dated: January 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00898 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vascular and Hematology Integrated Review Group; Integrative Vascular Physiology and Pathology Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 9:00 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: Bukhtiar H. Shah, DVM, MS, Ph.D., Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular, Molecular and Integrative Reproduction Study Section.

Date: February 17–18, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anthony Wing Sang Chan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 809K, Bethesda, MD 20892, (301) 496–9392, *chana2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Immuno-Oncology Research.

Date: February 22–23, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria Elena Cardenas-Corona, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309, *maria.cardenas-corona@nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis, Thrombosis, Blood Cells and Transfusion Study Section.

Date: February 22–23, 2022.

Time: 10:00 a.m. to 9:00 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: Ai-Ping Zou, M.D., Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, (301) 408–9497, *zouai@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Digestive System Host Defense, Microbial Interactions and Immune and Inflammatory Disease Study Section.

Date: February 24–25, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiping Zhao, M.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, Bethesda, MD 20892–7818, (301) 435–0682, *zhaoa2@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Hepatobiliary Pathophysiology Study Section.

Date: February 24–25, 2022.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301–827–4417, *jianxinh@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Emerging Imaging Technologies and Applications Study Section.

Date: February 24–25, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lawrence Edward Kagemann, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–6849, *larry.kagemann@nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Immunopathology and Immunotherapy Study Section.

Date: February 24–25, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zhang-Zhi Hu, M.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594–2414, *huzhuang@csr.nih.gov.*

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Cellular and Molecular Immunology—B Study Section.

Date: February 24–25, 2022.

Time: 9:00 a.m. to 9:00 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: Liying Guo, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, (301) 827–7728, *lguo@mail.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neuronal Communications Study Section.

Date: February 24–25, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–537–9986, *macarthurlh@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

Date: February 24–25, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Angela Y. Ng, MBA, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301–435–1715, *ngan@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

Date: February 24–25, 2022.

Time: 9:30 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shivani Sharma, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 507–7661, *shivani.sharma@nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group; Developmental Therapeutics Study Section.

Date: February 24–25, 2022.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nicholas J. Donato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040, Bethesda, MD 20892, 301–827–4810, *nick.donato@nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Interoception and Chemosensation Study Section.

Date: February 24–25, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892 (301), 408–9664, *bishopj@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: January 13, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00962 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: February 10–11, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rochelle Francine Hentges, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000C, Bethesda, MD 20892, (301) 402–8720, *hentgesrf@mail.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group; Radiation Therapeutics and Biology Study Section.

Date: February 14–15, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Science of Implementation in Health and Healthcare Study Section.

Date: February 15–16, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480–8667, *wangw22@mail.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Community Influences on Health Behavior Study Section.

Date: February 15–16, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pia Kristiina Peltola, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–9295, *pia.peltola@nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert Gersch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 867–5309, *robert.gersch@nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Interdisciplinary Clinical Care in Specialty Care Settings Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer,

Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov*.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mary G. Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301–915–6301, *marygs@csr.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Nanotechnology Study Section.

Date: February 17–18, 2022.

Time: 9:30 a.m. to 9:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov*.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Bioengineering of Neuroscience, Vision and Low Vision Technologies Study Section.

Date: February 17–18, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Immunity and Host Defense Study Section.

Date: February 17–18, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4203, Bethesda, MD 20892, (301) 435–3566, *mulkya@mail.nih.gov*.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Tumor Progression and Metastasis Study Section.

Date: February 17–18, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718, *jakobir@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bioengineering, Cellular and Circuit Neuroscience.

Date: February 18, 2022.

Time: 9:00 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: Jyothi Arikkath, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, Bethesda, MD 20892, (301) 435–1042, *arikkathj2@mail.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Injury, Repair, and Remodeling Study Section.

Date: February 22–23, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Digestive and Nutrient Physiology and Diseases Study Section.

Date: February 22–23, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aster Juan, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–435–5000, *juana2@mail.nih.gov*.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: February 22–23, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@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: January 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00897 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed 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: National Institute of Child Health and Human Development Special Emphasis Panel; Biobehavior.

Date: March 4, 2022.

Time: 5:00 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Health, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20892, (301) 435–6680, *skandasa@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Population Sciences Study Section/Archiving and Documenting Child Health and Human Development Data Sets.

Date: March 7, 2022.

Time: 3:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Health, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20892, (301) 451–4989, *crobbins@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Pelvic Floor Disorders Network (UG1 Clinical Research).

Date: March 17, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Luis E. Dettin, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 827–8231, *luis_dettin@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Pelvic Floor Disorders Network (U24 Resource-Related Research Projects).

Date: March 18, 2022.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Luis E. Dettin, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 827–8231, *luis_dettin@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 13, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00963 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Knock Out Mouse Phenotyping Program (KOMP2).

Date: March 10, 2022.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892, 301–402–8837, *barbara.thomas@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00900 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Patient-Oriented Research Study Section.

Date: March 3–4, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Stephanie Johnson Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–V, Bethesda, MD 20892, (301) 827–7992, *stephanie.webb@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00899 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Study Section.

Date: March 3–4, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–A, Bethesda, MD 20892–7924, (301) 827–7912, *copeka@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–00901 Filed 1–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act. To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Project: Revision of Mental Health Client/Participant Outcome Measures and Infrastructure, Prevention, and Mental Health Promotion Indicators (OMB No. 0930–0285)

SAMHSA is requesting approval from the Office of Management and Budget (OMB) for revisions to the previously approved instruments and data collection activities for the Government Performance and Results Act (GPRA) Center Mental Health Services (OMB No 0930–0285) that expires on February 28, 2022.

To be fully accountable for the spending of federal funds, SAMHSA requires all programs to collect and report data to ensure that program goals and objectives are met. Data is collected and used to monitor and improve performance of each program and ensure appropriate and thoughtful spending of federal funds.

SAMHSA requests the following revisions to the NOMS Mental Health Client/Participant Outcome measures: (1) Merge the CMHS NOMS Child Client-level Measures for Discretionary Programs data collection instrument with the current CMHS NOMS Adult Client-level Measures for Discretionary Programs data collection instrument; (2) delete questions for data not being utilized for program monitoring and quality improvement; (3) reduce grantee burden by shifting questions for a five-point psychometric response scale to ''Yes'', ''No'', and ''No response/Refused'' responses; (4) modify IDC–10 diagnoses to expand the F 40–48, F60–63, and F90–99 codes to allow for more specificity. Also, add ICD–10 ''Z'' codes to allow for a focus on social determinants of health that may affect the diagnosis, course, prognosis, or treatment of a client/consumer mental disorder; (6) shift reporting NOMS data to baseline assessment, 3-month or 6-month reassessment, and a final clinical discharge assessment; (7) reduce the number of physical health indictors and reporting frequency from quarterly to three points in time (baseline, 3- or 6-month reassessment, clinical discharge).

SAMHSA also requests the following revisions to the Infrastructure, Prevention, and Mental Health Promotion indicators:

(1) Delete four indicators not used by any SAMSHA programs: PD1: The number of policy changes completed as a result of the grant; WD4: The number of changes made to credentialing and licensing policies in order to incorporate expertise needed to improve mental health-related practices/activities; F1: The amount of additional funding obtained for specific mental health-related practices/activities that are consistent with the goals of the grant; and O2: The total number of contacts made through program outreach efforts).

(2) Revise two indicators to provide more clarity A3: The number of communities that enhance health information-sharing for provision of services between agencies and program; and A1: The number of grant project activities in which fidelity is monitored as a result of the grant); and

(3) Add eleven indicators to reflect program developments during the past three years: R2: The number of individuals referred to trauma-informed care services as a result of the grant; R3: The number of individuals referred to crisis or other mental health services for suicidality; S2: The number of individuals screened for trauma-related experiences as a result of the grant; S3: The number of individuals screened for suicidal ideation as a result of the grant; T5: The number of activities modified, adapted, or changed to reflect trauma-informed practices for the population(s) being served by the grant; T6: The number of activities modified, adapted, or changed to reflect culturally appropriate services for the population(s) being served by the grant; T7: As a result of the grant, reduce the percentage of individuals who died by suicide; and T8: As a result of the grant, reduce the number of individuals who attempted suicide).

These changes will lessen grantee burden with data collection and improve capacity to report qualitative performance and quantitative outcomes for all discretionary grant programs, including: Demographic characteristics of clients' served; clinical characteristics of clients' served before, during, and after receipt of services; numbers of clients served; and characteristics of services and activities provided to clients'.

Currently, the information collected from this instrument is entered and stored on SAMHSA's Performance Accountability and Reporting System (SPARS), a real-time, performance management system that captures information on mental health and substance abuse treatment services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance.

SAMHSA and its Centers will use the data collected for annual reporting required by required by GPRMA, to describe and understand changes in outcomes from baseline to follow-up to discharge. SAMHSA and its Centers will use the data for annual reporting comparing baseline with discharge and follow-up data. SAMHSA's report for each fiscal year will include actual results of performance monitoring for the three preceding fiscal years. Information collected through this request will allow SAMHSA to report on the results of these performance outcomes as well as be consistent with SAMHSA-specific performance domains, and to assess the

accountability and performance of its discretionary and formula grant programs. The additional information collected through this request will allow SAMHSA to improve its ability to assess the impact of its programs on key outcomes of interest and to gather vital diagnostic information about clients served by discretionary grant programs.

The requested changes will result in a reduction of total burden hours. Currently, there are 104,168 total burden hours in the OMB-approved inventory. SAMSHA is requesting a reduction to 68,673 hours or an estimated decrease of 35,494 burden hours. The proposed estimate of time to collect data and complete the instruments is shown in Table 1.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

SAMHSA tool	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Client-level baseline interview	40,280	1	40,280	0.33	30,901
Client-level 3- or 6-month reassessment interview	40,280	1	40,280	0.33	30,901
Client-level clinical discharge interview	6,668	1	6,668	0.33	2,200
Section H Physical Health Data Baseline	39,231	1	39,231	.10	3,923
Section H Program Specific Data: Baseline, 3- or 6-month reassessment, and clinical discharge	14,800	2	29,600	.08	2,368
Subtotal	141,259		154,059		68,673
Infrastructure development, prevention, and mental health promotion quarterly record abstraction	942	4	3,768	2.0	7,536
Total	142,201		157,827		104,168

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.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–00858 Filed 1–18–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Assessment of Communities Talk To Prevent Underage Drinking—(OMB No. 0930–0288)—Reinstatement

The Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Prevention (SAMHSA/CSAP) is requesting a reinstatement from the Office of Management and Budget (OMB) of information collection regarding the Assessment of *Communities Talk to Prevent Underage Drinking,* which is implemented by the Underage Drinking Prevention Education Initiatives (UADPEI) within CSAP. The most recent data collection was approved under OMB No. 0930–0288, Assessment of the Town Hall Meetings on Underage Drinking Prevention, which expired on May 31, 2020. Revisions were made to the Organizer Survey; it can be completed twice, namely after a round of *Communities Talk* events/activities (activities) from February 2022 to April 2022, and as a follow-up one year later from February 2023 to April 2023. The Organizer Survey—6 month Follow-up and Participant Form (English and Spanish versions) were dropped.

Changes

Under the most recent approval, the Organizer Survey consisted of 20 items. Under this revision, the Organizer Survey includes 14 items about the *Communities Talk* initiative and how communities might be carrying out evidence-based strategies to prevent underage drinking (UAD). The following table provides a summary of the changes that were made to the instrument.

Current question/item	Changes made
q1—Date of the Communities Talk event	Question deleted.
q2—Enter the location of the Communities Talk event	Question deleted.
q3—How long did the Communities Talk event last (*e.g.,* 45 minutes, 1.5 hours)?	Question deleted.
q4—How would you characterize the location where the Communities Talk event was held?	New q12.

Current question/item	Changes made
q5—What influenced your organization's decision to host a Communities Talk event? (Mark all that apply.)	Question deleted.
q6—Did any other community-based organization (*e.g.,* business, school) collaborate with your organization in hosting this event?	Question deleted.
q7—Were youth involved in organizing and/or hosting the Communities Talk event?	Question deleted.
q8—How was the Communities Talk event promoted? (Mark all that apply.)	Question deleted.
q9—What was the total number of attendees at the Communities Talk event? (Estimates are okay.)	New q3.
q10—In what language was the Communities Talk event conducted? (Mark all that apply.)	Question deleted.
q11—Which of the following best represents key speakers at the Communities Talk event? (Mark all that apply.)	Question deleted.
q12—Was underage drinking the only topic addressed by the Communities Talk event?	Question deleted.
q13—Which of the following alcohol-related topics were discussed at the Communities Talk event? (Mark all that apply.)	Question deleted.
q14—In your opinion, how important is underage drinking, and its consequences, to the residents of your community?	New q1.
q15—In the future, how likely is it that you or your organization will plan or collaborate with others on the following activities to prevent underage drinking in your community?	Added the following introductory sentence: 'A community's needs and its resources may change over time.' (new q9).
q16—Thinking about you and your organization, please rate your agreement with the following statements.	Deleted the following statements: (a) 'The Communities Talk event has increased my ability to share information about the importance of preventing underage drinking'; (b) 'As a result of this Communities Talk event, I feel more motivated to continue to address underage drinking in my community'; (c) 'As a result of this Communities Talk event, I feel more confident hosting another Communities Talk or other underage drinking prevention event in the future'; (d) 'As a result of this Communities Talk event, I am more likely to host another underage drinking prevention event in my community' (new q6).
q17—Did you use any material(s) from *www.stopalcoholabuse.gov/townhallmeetings* for the Communities Talk event? <If yes> What material(s) did you use?	In first sentence, replaced 'Did you use' with 'Have you used' and added 'the Communities Talk website'; In first sentence, deleted 'for the Communities Talk event'; In second sentence, replaced 'did you use' with 'have you used' and added 'the Communities Talk website' (new q5). Added a second question (new q5A) to replace '<If yes> What material(s) did you use?' with response options. New question reads: 'Q5A If <Q5=Yes> What material(s) from the Communities Talk website (*www.stopalcoholabuse.gov/communitiestalk*) have you used?. ○ Quick Start Planning Guide. ○ Registration Tutorial Video. ○ Tips & Tools for Hosting a Virtual Activity (*e.g.,* virtual activity starters and ideas). ○ Using Social Media guides. ○ Social Media Images/Graphics. ○ Customizable Resources for Communities Talk Promotion and Implementation (*e.g.,* PowerPoint template, flyer, logo, web badge). ○ Other (please specify) _____.
SAMHSA provides periodic webinars and online training at *www.stopalcoholabuse.gov/townhallmeetings* for organizations hosting Communities Talk events. SAMHSA also provides technical assistance to organizations through *www.stopalcoholabuse.gov/townhallmeetings/contact-us.aspx, info@stopalcoholabuse.net, eval@stopalcoholabuse.net,* and by telephone at (866) 419–2514..	Explanation and question deleted.
q18—Please rate your agreement with the following statements regarding any training or technical assistance (TA) that you or your organization received.	
q19—Please share any other important features or reactions to the Communities Talk event.	Question deleted.
q20—Did your organization develop a report, or does it plan to, that includes underage drinking data at the community level (*e.g.,* incidences of use; activities or actions employed to prevent and combat underage drinking)? <If yes> Would you be willing to share the report with SAMHSA? <If yes> Please send the report to the following address: *eval@stopalcoholabuse.net* [or] ICF, Attn.: Communities Talk on UAD—Renáa A. Agee, 530 Gaither Rd., Suite 500, Rockville, MD 20857.	In first sentence, replaced 'Did your organization develop a report, or does it plan to,' with 'Do you have a report or something else (*e.g.,* tables)'; In third sentence, replaced '*eval@stopalcoholabuse.net*' with '*info@stopalcoholabuse.net*'; In third sentence, replaced 'Communities Talk on UAD—Renáa A. Agee' with 'Communities Talk—Genevieve Martinez-Garcia' (new q11).

Current question/item	Changes made
<ALL ENDING> SAMHSA would like to contact you in about 6 months to follow up on any actions that were taken as a result of the Communities Talk event that was hosted in your community. Are you willing to be contacted in about 6 months to complete an online follow-up survey?	In first sentence, replaced '6 months' with '1 year'; In first sentence, replaced 'follow up on any actions that were taken as a result of the Communities Talk event that was hosted' with 'get an update on prevention activities taking place'; In second sentence, replaced '6 months' with '1 year'.
<EXIT screen 1 (Yes to recontact)> Thank you again for sharing this important information about the Communities Talk: Town Hall Meetings to Prevent Underage Drinking event that was held in your community! We will contact your organization in about 6 months to follow up on any actions that were taken as a result of the Communities Talk event that was held in your community.	In first sentence, replaced 'the Communities Talk: Town Hall Meetings to Prevent Underage Drinking event that was held in your community' with 'your experience with Communities Talk and underage drinking prevention activities'; At end, replaced 'REDIRECT TO *www.stopalcoholabuse.gov/townhallmeetings'* with 'Visit *www.stopalcoholabuse.gov/communitiestalk/* for the most current updates.'.
REDIRECT TO *www.stopalcoholabuse.gov/townhallmeetings*.	
<EXIT screen 2 (No to recontact)> Thank you again for sharing this important information about the Communities Talk: Town Hall Meetings to Prevent Underage Drinking event that was held in your community!	In first sentence, replaced 'the Communities Talk: Town Hall Meetings to Prevent Underage Drinking event that was held' with 'your experience with Communities Talk and underage drinking prevention activities'; At end, replaced 'REDIRECT TO *www.stopalcoholabuse.gov/townhallmeetings'* with '*Visit www.stopalcoholabuse.gov/communitiestalk/* for the most current updates.'
REDIRECT TO *www.stopalcoholabuse.gov/townhallmeetings/*.	

Seven new questions were added pertaining to number of *Communities Talk* activities that have ever taken place in the community (q2), preparation (tied or not tied to *Communities Talk*) completed to help organizers carry out evidence-based strategies to prevent UAD in their community (q4), confidence to carry out tasks related to evidence-based prevention (q7), current work to carry out evidence-based strategies (q8), perceived efficacy of *Communities Talk* to enhance UAD prevention in the community (q10), type of organization represented by respondent (q13), and audiences targeted by respondent's organization (q14). Some of these items (*i.e.,* q4, q7, and q8) are modified versions of instruments validated by Chinman et al. (2008).

The revisions were necessary to better align the data gathered to the short-term and long-term outcomes of the *Communities Talk* activities for organizers, specifically:

Short-Term

- Increase staff's perceived threat of UAD to residents of the communities;
- Increase staff's knowledge related to using evidence-based approaches to carry out future UAD drinking prevention activities;
- Increase staff's perceived efficacy of *Communities Talk* to enhance UAD prevention in the community;
- Increase staff's skills related to using evidence-based approaches to carry out future UAD prevention activities, specifically share information about UAD with others host meetings or discussion groups; create committees, task forces, advisory boards, or other action groups; build coalitions; develop strategic plans; and advocate for policies
- Increase staff's self-efficacy related to using evidence-based approaches to carry out future UAD prevention activities; and
- Increase staff's intention related to using evidence-based approaches to carry out future UAD prevention activities.

Long-Term

- Increase staff's use of evidence-based approaches to carry out future UAD prevention activities.

While completing the initial Organizer Survey, staff of Community-Based Organizations and Institutions of Higher Education can opt in to be contacted 1 year later. If they do so, they will receive an invitation to complete the same online questionnaire 1 year later. This will enable SAMHSA to determine how organizers might have progressed toward the aforementioned short- and long-term outcomes. Note that the Organizer Survey (see Attachment 1) has replaced the Organizer Survey—6 month Follow-Up. This change enables SAMHSA to compare responses between the initial and follow-up time periods (*e.g.,* and thus determine whether the same skills have increased or decreased over time).

SAMHSA/CSAP will be responsible for collecting, compiling, analyzing, and reporting on information requested through these surveys.

The Participant Survey has been discontinued in alignment with SAMHSA's focus on organizers as the target audience of *Communities Talk* activities.

SAMHSA supports nationwide *Communities Talk* activities every other year. Collecting data on each round of *Communities Talk* activities and using this information to inform policy and measure impact connects with SAMHSA's Strategic Plan FY2019–FY2023, specifically ''Objective 3.2: Expand community engagement around substance use prevention, treatment, and recovery'' (SAMHSA, 2018). *Communities Talk* activities are intended to work at the grassroots level to raise awareness of the public health dangers of UAD and to engage communities in evidence-based prevention. Notably, *Communities Talk* activities provide a forum for communities to discuss ways they can best prevent UAD by reducing the availability of alcohol and by creating community norms that discourage demand.

SAMHSA will use the information collected to document the implementation efforts of this nationwide initiative, determine if the federally sponsored *Communities Talk* activities lead to additional activities within the community that are aimed at preventing and reducing UAD, identify what these activities may possibly include, and help plan for future rounds of *Communities Talk* events. SAMHSA intends to post online a summary document of each round of *Communities Talk* activities and present findings at national conferences attended by CBOs and IHEs that have hosted these activities and might host future activities. Similarly, SAMHSA plans to share findings with the Interagency Coordinating Committee on the Prevention of Underage Drinking. Agencies within this committee encourage their grantees to participate as the activity hosts. Additionally, the information collected will support performance measurement for SAMHSA programs under the Government Performance Results Act (GPRA).

Data Collection Component

SAMHSA/CSAP will use a web-based method, such as Voxco, to collect data through the Organizer Survey. The web-based application will comply with the

requirements of Section 508 of the Rehabilitation Act to permit accessibility to people with disabilities.

From February 2022 to April 2022, the Organizer Survey—Initial will be completed by an estimated 500 Communities Talk activity organizers and will require only one response per respondent. It will take an average of 10 minutes (0.167 hours) to review the instructions and complete the survey. Similarly, from February 2023 to April 2023, the Organizer Survey—Follow-up will be completed by an estimated 500 Communities Talk activity organizers and will require only one response per respondent. It will take an average of 10 minutes (0.167 hours) to review the instructions and complete the survey. This burden estimate is based on comments from three 2019 Communities Talk activity organizers who reviewed the survey and provided comments on how long it would take them to complete it.

ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Organizer Survey—Initial	500	1	500	0.167	83.50
Organizer Survey—Follow-Up	500	1	500	0.167	83.50
Total	500		1,000		167.00

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57–A, Rockville, MD 20852 *OR* email him a copy at *carlos.graham@samhsa.hhs.gov.* Written comments should be received by March 21, 2022.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–00860 Filed 1–18–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Project: Mental and Substance Use Disorders Prevalence Study (MDPS) Grant Funded by SAMHSA, Grant Number H79FG000030

SAMHSA is requesting from the Office of Management and Budget (OMB) approval to conduct recruitment activities and clinical interviews with household respondents and non-household facilities and respondents as part of the Mental and Substance Use Disorders Prevalence Study (MDPS) pilot program. Activities conducted will include: A household rostering and mental health screening of household participants and a clinical interview of both household and non-household participants. The information gathered by the clinical interview will be used to determine prevalence estimates of schizophrenia or schizoaffective disorder; bipolar I disorder; major depressive disorder; generalized anxiety disorder; posttraumatic stress disorder (PTSD); obsessive-compulsive disorder; anorexia nervosa; and alcohol, benzodiazepine, opioid, stimulant, and cannabis use disorders among U.S. adults ages 18 to 65 years.

Household Rostering

The household rostering includes inquiries about all adults ages 18 and older residing in the household, to assess eligibility for inclusion in the study, and then selecting up to two adults for the household mental health screening. The total number of household members and numbers of adults and children are first asked, followed by the first name, age and sex of all adult household members, as well as whether any adult in the household has had a serious medical condition. The best time to be interviewed is collected as well. The computerized roster can be completed online, by phone, on paper, or in-person. The target population is adults ages 18–65 residing in U.S. households; it is estimated that 45,000 household rosters will be completed. The primary objective of the household roster is to select up to two age-eligible participants for the mental health screening interview.

Household Mental Health Screening

The household mental health screening interview utilizes the Computerized Adaptive Testing for Mental Health Disorders (CAT–MH) or the World Health Organization's Composite International Diagnostic Interview (CIDI) instruments to assess symptoms related to the mental health and substance use disorders of interest, including schizophrenia or schizoaffective disorder; bipolar I disorder; major depressive disorder; generalized anxiety disorder; posttraumatic stress disorder (PTSD); obsessive-compulsive disorder; anorexia nervosa; and alcohol, benzodiazepine, opioid, stimulant, and cannabis use. The screening instrument also includes questions on treatment, receipt of Social Security Disability Income (SSDI), military experience, and exposure to and impact of COVID–19. The computerized mental health screening can be completed online, by phone, on paper or in-person. The primary objectives of the household mental health screening interview are to assess the symptoms endorsed and determine eligibility and selection for the MDPS pilot program clinical interview.

Clinical Interview

The MDPS pilot program clinical interview includes questions that assess the mental health and substance use disorders using the NetSCID, a computerized version of the Structured Clinical Interview for DSM–V (SCID). This instrument includes questions on symptoms and their duration and frequency for the disorders of interest. Also collected from respondents is demographic information, including sex, gender, age, education and employment status. Hospitalization and treatment history are asked as well as questions to assess exposure to COVID–19 of self or other close family members and the impact on mental health. Up to two adults per household will be selected to complete the clinical interview. Participants from the prisons, jails, homeless shelters and state psychiatric hospitals will complete the clinical interview as well. The computer-assisted personal interview (CAPI) is administered by a trained clinical interviewer, and can be conducted by video conference, such as Zoom or WebEx, phone or in person. Approximately 7,200 clinical interviews will be conducted as part of the MDPS pilot program. The primary objective of the clinical interview is to estimate the prevalence of the disorders of interest, including schizophrenia or schizoaffective disorder; bipolar I disorder; major depressive disorder; generalized anxiety disorder; posttraumatic stress disorder (PTSD); obsessive-compulsive disorder; anorexia nervosa; and alcohol, benzodiazepine, opioid, stimulant, and cannabis use, as well as unmet treatment needs.

Jail Mental Health Screening

The jail mental health screening interview utilizes the CIDI screening instruments to assess symptoms related to the primary mental health and substance use disorders of interest including schizophrenia or schizoaffective disorder; bipolar I disorder; major depressive disorder; generalized anxiety disorder; posttraumatic stress disorder (PTSD); obsessive-compulsive disorder; anorexia nervosa; and alcohol, benzodiazepine, opioid, stimulant, and cannabis use. The screening instrument also includes questions on treatment, receipt of Social Security Disability Income (SSDI), military experience, and exposure to and impact of COVID–19. The computerized mental health screening will be completed in person or by phone. The target population is a convenience sample of incarcerated 18–65-year-old adults, in up to six jails identified by the MDPS co-investigator team. Up to 208 mental health screening interviews will be conducted among incarcerated respondents. Respondents will be provided with a card that includes contact information and asked to contact the project personnel when they are released for inclusion in the household clinical interview sample. The primary objective of the jail mental health screening interview is to determine the feasibility of conducting mental health screening interviews within a jail population, as well as whether they would have been included in the household sample during the data collection period should they not have been incarcerated.

Facility Recruitment

Information packets will be sent to all selected prisons, state psychiatric hospitals, homeless shelters and jails including a letter of invitation, letters of support, an overview of the project and an overview of the data collection process in the facility. Facilities will be contacted by telephone, to answer any questions and provide additional information regarding the MDPS pilot program. Once approval is obtained, a logistics manager will contact the facility to provide instructions on the rostering and selection processes, to schedule the data collection visit, and to determine the appropriate space to conduct the interviews and the number of days and hours per day for data collection. Facilities will be asked to provide a roster (deidentified or identified) of eligible residents within one week of scheduling the data collection visit and again one-to-two weeks prior to the actual data collection visit (note: Data collection can be scheduled up to 4 months in advance). At the time of data collection, facility staff will assist with data collection activities including escorting selected inmates to and from the data collection area.

The primary objective of the MDPS pilot program is to examine methods to estimate the prevalence of specific mental illnesses, particularly adults with psychotic disorders and serious functional impairment, and treatment in both populations to answer two core research questions:

- What is the prevalence of schizophrenia/schizoaffective disorder (lifetime and past year), bipolar I disorder (past year), major depressive disorder (past year), generalized anxiety disorder (past year), posttraumatic stress disorder (past year), obsessive-compulsive disorder (past year), anorexia nervosa (past year), and alcohol, benzodiazepine, opioid, stimulant, and cannabis use disorders (past year) among adults, ages 18–65, in the United States?
- What proportion of adults in the United States with these disorders received treatment in the past year?

In addition to these research questions, the MDPS pilot program will allow for procedural evaluation to:

- Identify which set of screening instruments might be best to accurately identify mental and substance use disorders within the U.S. household population;
- Understand the best approaches to conducting data collection within non-household settings, to gather information on mental illness and treatment;
- Design protocols for collecting clinical interviews from proxy respondents; and
- Establish a protocol that can be used at a larger scale to understand the prevalence and burden of specific mental disorders in both non-household and household populations across the United States.

EXHIBIT 1—TOTAL ESTIMATED ANNUALIZED RESPONDENT BURDEN BY INSTRUMENT AND FACILITY RECRUITMENT

Activity	Total number of respondents	Number of responses per respondent	Total number of responses	Average hours per response	Average burden hours	Average hourly wage **	Total cost
Instrument:							
Household Rostering	45,000	1	45,000	0.13	5,850	$19.83	$116,006
Household contact attempts*	45,000	1	45,000	0.17	7,650	19.83	151,700
Household Screening	45,000	1	45,000	0.25	11,250	19.83	223,088
Screening contact attempts*	45,000	1	45,000	0.17	7,650	19.83	151,700
Clinical Interview (household and non-household)	7,200	1	7,200	1.40	10,080	19.83	199,886
Clinical Interview contact attempts*	7,200	1	7,200	0.25	1,800	19.83	35,694
Jail Screening Interview	208	1	208	0.33	69	19.83	1,369

EXHIBIT 1—TOTAL ESTIMATED ANNUALIZED RESPONDENT BURDEN BY INSTRUMENT AND FACILITY RECRUITMENT—Continued

Activity	Total number of respondents	Number of responses per respondent	Total number of responses	Average hours per response	Average burden hours	Average hourly wage**	Total cost
Jail Clinical Interview	63	1	63	1.40	88	19.83	1749
Sub-total Interviewing Estimates	.....	.....	.....	.....	44,437	.....	881,192
Facility Recruitment							
Information package review for facility administrators	58	1	58	0.75	43.5	25.09	1,091
Initial call with facility staff	58	1	58	1	58	25.09	1,455
Telephone call with facility staff to explain roster file process	58	1	58	2	116	25.09	2,910
Facility staff provides roster	58	4	232	2	464	25.09	11,642
Facility staff coordinates time and location for clinical interview administration	58	4	232	2	464	25.09	11,642
Sub-total Facility Recruitment Estimates	.....	.....	.....	.....	1,145.5	.....	28,740
Total	.....	.....	.....	.....	45,582.5	.....	909,932

*Contact attempts include the time spent reviewing all follow-up letters and study materials, including the respondent website, interactions with field and telephone interviewers, the consent process including asking questions regarding rights as a participant and receiving responses, and all other exchanges during the recruitment and interviewing processes.

**To compute total estimated annual cost for Interviewing, the total burden hours were multiplied by the average hourly wage for each adult participant, according to a Bureau of Labor Statistics (BLS) chart called ''Median usual weekly earnings of full-time wage and salary workers by educational attainment.'' (Median usual weekly earnings of full-time wage and salary workers by educational attainment (*bls.gov*)). We used the median salary for full-time employees over the age of 25 who are high school graduates with no college experience in the 2nd quarter of 2021 ($19.83 per hour). * For the Facility Recruitment, the total average burden assumes an average hourly rate of $25.09 for Community and Social Service Managers, given in the Bureau of Labor Statistic's Occupational Employment Statistics, May 2020.

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *Carlos.Graham@samhsa.hhs.gov.* Written comments should be received by March 21, 2022.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–00861 Filed 1–18–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Project: Government Performance and Results Act (GPRA) Client/Participant Outcomes Measure—(OMB No. 0930–0208)—Revision

SAMHSA is requesting approval to modify its existing CSAT Client-level GPRA instrument by removing 48 questions and adding 42 questions for a net decrease of six questions. In revising the CSAT–GPRA tool, we sought to improve functionality while also eliciting programmatic information that demonstrates impact at the client level. In this way, data from the revised GPRA tool can be used to assess resource allocation and to delineate who we serve, how we serve them, and how the program impacts clients from entry to discharge. Beyond this, much of the tool has been restructured to make its administration flow with greater ease, while also eliciting information that speaks to a client's experience with substance misuse, the concurrent use of substances and mental health. This is most apparent in Section B (Substance Use and Planned Services), where questions have been updated and restructured to elicit important aspects of a client's use of substances, namely the frequency of use and combinations of misused substances. This speaks to an emerging and urgent need to appropriately manage polysubstance misuse,[1] and the questions allow for evidence of change as the tool is readministered at different intervals. These questions do not rely on ICD–10 codes, so as to create a dialogue between the client and the individual administering the tool. Restructuring the tool has also included:

- Placing many questions from the general GPRA Tool, that have previously been viewed as being specific to patient populations or grants, in the menu items found in Section H. This section allows Program Officers the opportunity to introduce grant specific questions as needed;
- Removing or substantially altering existing questions viewed as being potentially traumatizing or incentive to clients;
- Removing questions that have not been used in program evaluation at the federal level; and
- Incorporating evidence-based questions from tools such as the Addiction Severity Index to better address program performance.

Currently, the information collected from this instrument is entered and stored in SAMHSA's Performance Accountability and Reporting System, which is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance.

SAMHSA will use the data for annual reporting required by GPRA and comparing baseline with discharge and follow-up data. GPRA requires that

[1] Substance Abuse and Mental Health Services Administration (SAMHSA): Treating Concurrent Substance Use Among Adults. SAMHSA Publication No. PEP21–06–02–002. Rockville, MD: National Mental Health and Substance Use Policy Laboratory. Substance Abuse and Mental Health Services Administration, 2021.

SAMHSA's fiscal year report include actual results of performance monitoring for the three preceding fiscal years. The additional information collected through this process will allow SAMHSA to: (1) Report results of these performance outcomes; (2) maintain consistency with SAMHSA-specific performance domains, and (3) assess the accountability and performance of its discretionary and formula grant programs.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

SAMHSA tool	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours	Hourly wage [1]	Total hour cost
Baseline Interview Includes SBIRT Brief TX, Referral to TX, and Program-specific questions	179,668	1	179,668	0.6	107,801	$24.78	$2,671,309
Follow-Up Interview with Program-specific questions [2]	143,734	1	143,734	0.6	86,240	24.78	2,137,027
Discharge Interview with Program-specific questions [3]	93,427	1	93,427	0.6	56,056	24.78	1,389,068
SBIRT Program—Screening Only	594,192	1	594,192	0.13	77,245	24.78	1,914,131
SBIRT Program—Brief Intervention Only Baseline	111,411	1	111,411	0.2	22,282	24.78	552,148
SBIRT Program—Brief Intervention Only Follow-Up [2]	89,129	1	89,129	0.2	17,826	24.78	441,728
SBIRT Program—Brief Intervention Only Discharge [3]	57,934	1	57,934	0.2	11,587	24.78	287,126
CSAT Total	1,269,495		1,269,495		379,037		9,392,537

[1] The hourly wage estimate is $21.23 based on the Occupational Employment and Wages, Mean Hourly Wage Rate for 21–1011 Substance Abuse and Behavioral Disorder Counselors = $24.78/hr. as of May 11, 2021. (*http://www.bls.gov/oes/current/oes211011.htm.* Accessed on May 11, 2021.)
[2] It is estimated that 80% of baseline clients will complete this interview.
[3] It is estimated that 52% of baseline clients will complete this interview.
Note: Numbers may not add to the totals due to rounding and some individual participants completing more than one form.

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.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–00857 Filed 1–18–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0122]

Screening Requirements for Carriers

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; revision of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than March 21, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0122 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions 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, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Screening Requirements for Carriers.

OMB Number: 1651–0122.

Form Number: N/A.

Current Actions: CBP proposes to extend the expiration date and revise this information collection to allow electronic submission. There is no change to the information collected.

Type of Review: Revision.

Affected Public: Carriers.

Abstract: Section 273(e) of the Immigration and Nationality Act (8 U.S.C. 1323(e)) (the Act) authorizes the Department of Homeland Security

(DHS) to establish procedures which carriers must undertake for the proper screening of their non-immigrant passengers prior to embarkation at the port from which they are to depart for the United States, in order to become eligible for a reduction, refund, or waiver of a fine imposed under section 273(a)(1) of the Act. (This authority was transferred from the Attorney General to the Secretary of Homeland Security pursuant to the Homeland Security Act of 2002.) To be eligible to obtain such a reduction, refund, or waiver of a fine, the carrier must provide evidence to U.S. Customs and Border Protection (CBP) that it screened all passengers on the conveyance in accordance with the procedures listed in 8 CFR part 273.

Some examples of the evidence the carrier may provide to CBP include: A description of the carrier's document screening training program; the number of employees trained; information regarding the date and number of improperly documented non-immigrants intercepted by the carrier at the port(s) of embarkation; and any other evidence to demonstrate the carrier's efforts to properly screen passengers destined for the United States.

Proposed Change: Applicants may submit this information via electronic means, *e.g.,* email.

Type of Information Collection: Screening Requirements for Carriers.

Estimated Number of Respondents: 41.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 41.

Estimated Time per Response: 100 hours.

Estimated Total Annual Burden Hours: 4,100.

Dated: January 13, 2022.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2022–00964 Filed 1–18–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2004–19147]

Revision of Agency Information Collection Activity Under OMB Review: Flight Training Security

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0021, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves the submission of identifying information for background checks for all non-U.S. citizens, non-U.S. nationals and other designated individuals seeking flight instruction (''candidates'') from Federal Aviation Administration (FAA)-certificated flight training providers. Through the information collected, TSA will determine whether a candidate is a threat to aviation or national security, and thus prohibited from receiving flight training. Additionally, flight training providers are required to conduct a security awareness program for their employees and contract employees and to maintain records associated with this training.

DATES: Send your comments by February 18, 2022. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 25, 2021, 86 FR 47507.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Flight Training Security.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0021.

Forms(s): N/A.

Affected Public: Candidates, as defined in 49 CFR 1552.1, seeking flight instruction from FAA-certificated flight training providers and flight training providers required to conduct security awareness training and their employees.

Abstract: This information collection relates to regulations issued by TSA for flight training providers. There are two parts to the collection. First, under 49 CFR part 1552, subpart A, the collection relates to the security threat assessments (STAs) that TSA requires to determine whether candidates are a threat to aviation or national security, and thus prohibited from receiving flight training. This collection of information requires FAA-certificated flight training providers to provide TSA with the information necessary to conduct the STAs. Second, under 49 CFR part 1552, subpart B, the collection relates to security awareness training for flight training provider employees and contract employees, which includes maintaining records of all such training.

TSA is revising the information collection by changing the name of the collection from ''*Flight Training for Aliens and Other Designated Individuals; Security Awareness Training for Flight School Employees*'' to ''*Flight Training Security.*''

Number of Respondents: 39,496.

Estimated Annual Burden Hours: An estimated 103,816 hours annually.[1]

[1] Since the publication of the 60-day notice, TSA has updated the burden hours from 99,564 to 103,816 annual hours.

Estimated Annual Cost Burden: $7,018,816.

Dated: January 10, 2022.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2022–00894 Filed 1–18–22; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0020]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Petition for Amerasian, Widow(er), or Special Immigrant

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until February 18, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2007–0024. All submissions received must include the OMB Control Number 1615–0020 in the body of the letter, the agency name and Docket ID USCIS–2007–0024.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on September 29, 2021, at 86 FR 53983, allowing for a 60-day public comment period. USCIS did receive four comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0024 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Amerasian, Widow(er), or Special Immigrant.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–360; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–360 may be used by an Amerasian; a widow or widower; a battered or abused spouse or child of a U.S. citizen or lawful permanent resident; a battered or abused parent of a U.S. citizen son or daughter; or a special immigrant (religious worker, Panama Canal company employee, Canal Zone government employee, U.S. government employee in the Canal Zone; physician, international organization employee or family member, juvenile court dependent; armed forces member; Afghanistan or Iraq national who supported the U.S. Armed Forces as a translator; Iraq national who worked for the or on behalf of the U.S. Government in Iraq; or Afghan national who worked for or on behalf of the U.S. Government or the International Security Assistance Force [ISAF] in Afghanistan) who intend to establish their eligibility to immigrate to the United States. The data collected on this form is reviewed by U.S. Citizenship and Immigration Services (USCIS) to determine if the petitioner may be qualified to obtain the benefit. The data collected on this form will also be used to issue an employment authorization document upon approval of the petition for battered or abused spouses, children, and parents, if requested.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Petition for Amerasian, Widower, or Special Immigration (Form I–360); *Iraqi & Afghan Petitioners* is 2,874 and the estimated hour burden per response is 3.1 hours; the estimated total number of respondents for the information collection Petition for Amerasian, Widower, or Special Immigration (Form I–360); *Religious Workers* is 2,393 and the estimated hour burden per response is 2.35 hours; the estimated total number of respondents

for the information collection Petition for Amerasian, Widower, or Special Immigration (Form I–360); *All Others* is 14,362 and the estimated hour burden per response is 2.1 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 44,693 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $2,404,430.

Dated: January 11, 2022.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–00941 Filed 1–18–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–NEW]

Agency Information Collection Activities; New Collection: Petition for a Nonimmigrant Worker: H–1 Classifications

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until February 18, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2021–0015. All submissions received must include the OMB Control Number 1615–NEW in the body of the letter, the agency name and Docket ID USCIS–2021–0015.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on August 18, 2021, at 86 FR 46263 allowing for a 60-day public comment period. USCIS received twelve comments in connection with the 60-day notice.

USCIS made edits to the I–129H1 Form and Instructions in response to comments. USCIS also removed form items and instructional language that were associated with the final rule published on January 8, 2021 titled, *Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H–1B Petitions* (86 FR 1676) (H–1B Selection Final Rule). That rule was withdrawn on December 22, 2021 via publication of a final rule in the **Federal Register** titled *Modification of Registration Requirement for Petitioners Seeking To File Cap-Subject H–1B Petitions, Implementation of Vacatur* (86 FR 72516), as were information collection elements associated with that rule that would have gone into effect had the rule not been withdrawn. Therefore, the form items and instructional language associated with the January 2021 final rule that were included in the 60-day notice version of Form I–129H1 are not being implemented.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2021–0015in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Petition for a Nonimmigrant Worker: H–1 Classifications.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–129H1; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. USCIS will use the data collected on this form to determine eligibility for the requested nonimmigrant classification and/or requests to extend or change nonimmigrant status. An employer (or agent, where applicable) uses this form to petition USCIS for a noncitizen to temporarily enter the United States as an H–1B or H–1B1 nonimmigrant. An employer (or agent, where applicable) also uses this form to

request an extension of stay of an H–1B or H–1B1 nonimmigrant worker or to change the status of a beneficiary currently in the United States as a nonimmigrant to H–1B or H–1B1. The form serves the purpose of standardizing requests for H–1B and H–1B1 nonimmigrant workers and ensuring that basic information required for assessing eligibility is provided by the petitioner while requesting that beneficiaries be classified under the H–1B or H–1B1 nonimmigrant employment categories. USCIS compiles data from this form to provide information required by Congress annually to assess the effectiveness and utilization of certain nonimmigrant classifications. Data collected on employers petitioning for H–1B beneficiaries is provided to the media, researchers, and the general public via the H–1B Employer Data Hub.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form I–129H1 is 402,034 and the estimated hour burden per response is 4 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,608,136 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $207,047,510.

Dated: January 13, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–00942 Filed 1–18–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0063]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: National Interest Waiver; Supplemental Evidence to I–140 and I–485

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until March 21, 2022.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0063 in the body of the letter, the agency name and Docket ID USCIS–2008–0003. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2008–0003.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2008–0003 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* National Interest Waiver; Supplemental Evidence to I–140 and I–485.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No form number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The supplemental documentation will be used by the U.S. Citizenship and Immigration Services to determine eligibility for national interest waiver requests and to finalize the request for adjustment to lawful permanent resident status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection of the National Interest Waiver is 8,000 who are required to submit the information twice, at the second- and sixth-year anniversaries of the USCIS Form I–140 approval, and the

estimated hour burden per response is 1 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 16,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0. Costs for this collection of information are included in those reported for USCIS Form I–485 (OMB Control Number 1615–0023) and USCIS Form I–140 (OMB Control Number 1615–0015).

Dated: January 11, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–00944 Filed 1–18–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0137]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Employment Authorization for Abused Nonimmigrant Spouse

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until February 18, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2016–0004. All submissions received must include the OMB Control Number 1615–0137 in the body of the letter, the agency name and Docket ID USCIS–2016–0004.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on October 29, 2021, at 86 FR 60060, allowing for a 60-day public comment period. USCIS received two comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2016–0004 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Employment Authorization for Abused Nonimmigrant Spouse.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–765V; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. USCIS uses Form I–765V, Application for Employment Authorization for Abused Nonimmigrant Spouse, to collect the information needed determine if the applicant is eligible for an initial EAD or renewal EAD as a qualifying abused nonimmigrant spouse. Noncitizens are required to possess an EAD as evidence of work authorization. To be authorized for employment, a noncitizen must be lawfully admitted for permanent residence or authorized to be so employed by the INA or under regulations issued by DHS. Pursuant to statutory or regulatory authorization, certain noncitizens are authorized to be employed in the United States without restrictions as to location or type of employment as a condition of their admission or subsequent change to one of the indicated classes. USCIS may determine the validity period assigned to any document issued evidencing a noncitizen's authorization to work in the United States. USCIS also collects biometric information from EAD applicants to verify their identity, check or update their background information, and produce the EAD card.

(5) *An estimate of the total number of respondents and the amount of time*

estimated for an average respondent to respond: The estimated total number of respondents for the information collection I–765V is 350 and the estimated hour burden per response is 3.75 hours; the estimated total number of respondents for the information collection Biometric Processing is 350 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,723 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $87,500.

Dated: January 11, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–00940 Filed 1–18–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6310–N–01]

Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act

AGENCY: Office of Chief Financial Officer, HUD.

ACTION: Notice.

SUMMARY: This notice announces that the Department of Housing and Urban Development (HUD, the Department) has conducted an initial review required by the Build America, Buy America Act (the Act) to identify and evaluate its Federal financial assistance programs for infrastructure to determine whether they are inconsistent with the Infrastructure Investment and Jobs Act (the IIJA). The Act imposes domestic content procurement preference requirements on Federal financial assistance programs for infrastructure that do not currently have such a requirement and requires Federal agencies to evaluate each financial assistance program for infrastructure administered by the agency to identify programs inconsistent with the Act's requirements for application of a domestic procurement preference. Each Federal agency must submit its report on the agency's programs and related determinations to Congress and to the Office of Management and Budget (OMB) and publish its report in the **Federal Register**. Today's notice complies with the Act's publication and reporting requirements and contains HUD's list of identified Federal financial assistance programs for infrastructure. HUD has determined that none of the programs it has reviewed to date are consistent with the Act. HUD's initial analysis errs on the side of over-inclusiveness based on the Department's current understanding of information contained in the Act and the imminent timing requirements for reporting.

FOR ADDITIONAL INFORMATION CONTACT: J. Malcom Smith, Management and Program Analyst, Grants Management and Oversight Division, Office of the Assistant Chief Financial Officer of Systems, Office of the Chief Financial Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–8000; telephone number 202–402–6472 (this is not a toll-free number), or email *AskGMO@hud.gov* with the subject line ''Build America, Buy America''. Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: On November 15, 2021, the President signed into law the Infrastructure Investment and Jobs Act (Pub. L. 117–58) (the IIJA), which includes the Build America, Buy America Act at sections 70911 through 70927 (the Act). The Act ensures that Federal financial assistance programs for infrastructure require the use of materials produced in the United States, increases requirements for American-made content, and strengthens the waiver process associated with Buy American provisions. Section 70913 of the Act requires, within 60 days of the enactment of the IIJA, that each Federal agency, including HUD,[1] file a report with Congress and the Office of Management and Budget (OMB) which identifies and evaluates all financial assistance programs for infrastructure to determine whether the program is inconsistent with section 70914 of the Act. The report must be published in the **Federal Register**. The reports must identify and provide a list of which of these programs are ''deficient,'' as defined in section 70913(c) of the Act.[2]

Section 70914 of the Act requires that no later than 180 days after enactment of the IIJA (which would be May 14, 2022), Federal agencies ''shall ensure that none of the funds made available for a Federal financial assistance program for infrastructure, including each deficient program, may be obligated for a project unless all of the iron, steel, manufactured products, and construction materials used in the project are produced in the United States.'' [3] Federal agencies must identify all infrastructure programs and determine whether a program is inconsistent with section 70914 of the Act, regardless of whether the program received funding from IIJA. (HUD did not receive funding.) Pursuant to the Act, an infrastructure program is considered inconsistent with section 70914 if: (1) It does not require that all the iron, steel, manufactured products, and construction materials used in the project are produced in the United States; (2) it does not issue waivers and written justifications as specified in section 70914; or (3) it is subject to a waiver of general applicability under section 70914(b) of the Act. On December 20, 2021, OMB issued a memorandum titled ''Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act,'' M–22–08, to implement these requirements and provide guidance to Federal agencies.[4]

HUD awards discretionary funding through over 20 Grant programs and 10 formula programs in support of HUD's mission. These programs generally meet the definition of ''Federal financial assistance'' as defined in the Act. HUD has evaluated these programs and they are included in this report, but a full assessment of whether they fund infrastructure as described by the Act has not yet been completed. HUD has

[1] The Act applies to ''any authority of the United States that is an ''agency'' as defined in 44 U.S.C. 3502. Public Law 117–58, section 70912(3).

[2] The Act defines ''deficient programs'' as ''any Federal financial assistance program for infrastructure . . . for which a domestic content procurement preference requirement does not apply in a manner consistent with section 70914 of the law; or is subject to a waiver of general applicability not limited to the use of specific products for use in a specific project.'' *Id.* at section 70913(c).

[3] Section 70912(4) of the Act defines ''Federal financial assistance'' and provides that the definition is consistent with the definition in 2 CFR 200.1 and includes ''all expenditures by a Federal agency to a non-Federal entity for an infrastructure project, except that it does not include expenditures for assistance authorized under section 402, 403, 404, 406, 408, or 502 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170a, 5170b, 5170c, 5172, 5174, or 5192) relating to a major disaster or emergency declared by the President under section 401 or 501, respectively, of such Act (42 U.S.C. 5170, 5191) or pre and post disaster or emergency response expenditures.''

[4] Available at *https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-08.pdf.*

determined that no programs reviewed to date fully meet the requirements outlined in section 70914 of the Act. Details on each of these programs and the programs are listed below are included on a spreadsheet that can be accessed at: *https://www.hud.gov/program_offices/spm/gmomgmt/grantsinfo/fundingopps.* HUD's initial analysis errs on the side of over-inclusiveness, as recommended by OMB Memorandum M–22–08, based on the Department's current understanding of information contained in the Act and the imminent timing requirements for reporting.

Discretionary Programs

Office of Community Planning and Development

- Self-Help Homeownership Opportunity Program (SHOP)
- Community Development Technical Assistance
- Section 4 Capacity Building for Community Development and Affordable Housing.
- Tribal HUD–VASH Program for Community Development and Affordable Housing
- Office of Fair Housing and Equal Opportunity
- Fair Housing Assistance Program (FHAP) State and Local
- Fair Housing Initiatives Program for Education and Outreach
- Fair Housing Initiatives Program for Private Enforcement Initiatives
- Fair Housing Initiatives Program for Fair Housing Organization Initiatives

Office of Healthy Homes Lead Hazard Control

- Lead-Based Paint Hazard Control in Privately Owned Housing
- Lead and Healthy Homes Technical Studies
- Healthy Homes and Weatherization Cooperation Demonstration
- Healthy Homes Production Grant Program
- Lead Hazard Reduction Demonstration Grant Program
- Older Adults Modification Grant Program

Office of Housing

- Multifamily Housing Service Coordinator Grant Program
- Congregate Housing Services Program
- Project Rental Assistance Demonstration (PRA Demo) Program of Section 811 Supportive Housing for Persons with Disabilities
- Supportive Service Demonstration Program for Elderly Housing

Office of Policy Development and Research

- Research and Evaluations, Demonstrations, and Data Analysis and Utilization

Office of Public and Indian Housing

- Family Self Sufficiency
- Resident Self Sufficiency Service Coordinators
- Juvenile Re-entry Assistance Program
- Choice Neighborhood Planning
- Community Development Block Grant Indian Tribes and Alaska Native Villages
- Jobs Plus Pilot
- Choice Neighborhoods Implementation

Non-Discretionary Programs

Office of Community Planning and Development

- Community Development Block Grants/Entitlement Grants
- Community Development Block Grants/State's program and Non-Entitlement Grants in Hawaii
- Emergency Solutions Grant Program
- Home Investment Partnerships Program
- Housing Opportunities for Persons with AIDS
- Housing Trust Fund

Office of Public and Indian Housing

- Tribal HUD–VASH Program
- Indian Housing Block Grants
- Public Housing Capital Fund

George Tomchick,

Deputy Chief Financial Officer, Office of the Chief Financial Officer.

[FR Doc. 2022–01071 Filed 1–14–22; 4:15 pm]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CONC–32679; PPWOBSADC0, PPMVSCS1Y.Y00000]

Notice of Intent To Award a Sole-Source Concession Contract for Fire Island National Seashore

AGENCY: National Park Service, Interior.

ACTION: Notice of proposed award of sole-source concession contract for Fire Island National Seashore.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a sole-source concession contract for the conduct of certain visitor services within Fire Island National Seashore. The visitor services include marina operations, campground operations, food and beverage, and retail.

DATES: The term of the sole-source concession contract will commence (if awarded) no earlier than sixty (60) days from the publication of this notice, but the National Park Service intends for the term to begin January 1, 2022 (estimated) and end December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Kurt Rausch, Program Chief, Commercial Services Program, National Park Service, 1849 C Street NW, Mail Stop 2410, Washington, DC 20240; Telephone: 202–513–7156.

SUPPLEMENTARY INFORMATION: Pursuant to 36 CFR 51.25, the Director of the National Park Service (Service) may award a concession contract non-competitively upon a determination that extraordinary circumstances exist under which compelling and equitable considerations require the award of the concession contract to a particular qualified person in the public interest and that such an award is otherwise consistent with the requirements of part 51. Contracts that are awarded non-competitively under this authority are commonly referred to as ''sole-source'' contracts. The Service has determined that the proposed award of a sole-source contract to Love Watch Hill and Sailors Haven, Inc. is necessary based on the following information.

The extraordinary circumstances in this instance occurred after the Service issued a prospectus for a long-term contract and are a combination of the unanticipated failure of the docks' electrical system, the complete loss of the restaurant in the Watch Hill area, and the COVID–19 pandemic. The Service exhausted the time allowed for temporary contracts authorized under 36 CFR 51.24 while addressing these complications and recognized that the loss of the restaurant, combined with the COVID–19 pandemic, altered the financial assumptions for any long-term contract compared with those used to develop the prospectus to the extent that the Service no longer could award the draft 10-year contract offered in the prospectus.

The Service has determined that Love Watch Hill and Sailors Haven, Inc. is a ''qualified person'' as defined by 36 CFR 51.3, and has determined that compelling and equitable considerations exist with Love Watch Hill and Sailors Haven, Inc.'s continued provision of visitor services under stresses that would have deterred or even driven away many operators. Additionally, Love Watch Hill and Sailors Haven, Inc. holds the insurance proceeds to be used for the construction of the new restaurant.

The Service has determined that the award of a sole-source concession contract is in the public interest because otherwise there would be no concessioner providing the visitor services or maintaining the government-owned facilities for at least two years.

This is not a request for proposals. The publication of this notice reflects the intent of the Service but does not bind the Service to award the sole-source contract. Should the Service award the sole-source contract, the NPS will ensure such award is otherwise consistent with the requirements of part 51.

Justin Unger,

Associate Director, Business Services.

[FR Doc. 2022–00657 Filed 1–18–22; 8:45 am]

BILLING CODE 4312–53–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–33264; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before January 8, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by February 3, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before January 8, 2022. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

IOWA

Carroll County

Carroll City-Mount Olivet Cemetery, South Grant Rd., Carroll, SG100007432

KANSAS

Wabaunsee County

Mount Mitchell Heritage Prairie Historic District, 29377 Mitchell Prairie Ln., Wamego, SG100007422

MISSISSIPPI

Adams County

Spokane Mound Archaeological Site, Address Restricted, Natchez vicinity, SG100007425

Carroll County

Carrollton Water Tower, 100 Lexington St. Extended, Carrollton, SG100007424

Issaquena County

Blackwell, Unita, House, 139 Rosebud St., Mayersville, SG100007426

Warren County

CSA Powder Magazine and Site of Battery No. 4, 600 Fort Hill Dr., Vicksburg, SG100007427

MISSOURI

Randolph County

Commerce Bank, 208 West Reed St., Moberly, SG100007420

Warren County

Treloar Mercantile and Farmer's Bank of Treloar HD, 2 MKT St., Treloar, SG100007419

NEVADA

Clark County

Las Vegas High School Historic District, (Historic School Buildings in the Evolution of the Fifth Supervision School District MPS), 315 South 7th St., 925 East Clark Ave., Las Vegas, MP100007431

Washoe County

St. Thomas Aquinas Cathedral Complex, (Architecture of Frederick J. DeLongchamps TR), 310 West 2nd St., Reno, MP100007430

OHIO

Richland County

Dickey, Moses and Margaret, House, 159 North Walnut St., Mansfield, SG100007421

TEXAS

Dallas County

Gospel Lighthouse Church, 1900 South Ewing Ave., Dallas, SG100007423

A request for removal has been made for the following resource:

MISSOURI

Laclede County

Laclede County Jail, Adams and 3rd Sts., Lebanon, OT80002372

Additional documentation has been received for the following resources:

CALIFORNIA

Contra Costa County

Martinez Downtown Post Office (Additional Documentation), (US Post Office in California 1900–1941 TR), 815 Court St., Martinez, AD12000265

Martinez Downtown Post Office (Additional Documentation), (Martinez, California MPS), 815 Court St., Martinez, AD12000265

Contra Costa County Hall of Records (Additional Documentation), (Martinez, California MPS), 725 Court St., Martinez, AD91001385

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

MASSACHUSETTS

Hampden County

Springfield Armory (Additional Documentation), State, Federal, Pearl, and Byers Sts., Springfield, AD66000898

TENNESSEE

Rutherford County

Stones River National Battlefield (Boundary Increase), 3501 Old Nashville Hwy., Murfreesboro, BC100007434

Stones River National Battlefield (Additional Documentation), 3501 Old Nashville Hwy., Murfreesboro, AD66000075

Authority: Section 60.13 of 36 CFR part 60.

Dated: January 11, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2022–00893 Filed 1–18–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CONC–32683; PPWOBSADC0, PPMVSCS1Y.Y00000]

Notice of Intent To Award a Sole-Source Concession Contract for Yellowstone National Park

AGENCY: National Park Service, Interior.

ACTION: Notice of proposed award of a sole-source concession contract for Yellowstone National Park.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a sole-source concession contract for the conduct of certain visitor services within Yellowstone National Park. The visitor services include food and beverage and retail.

DATES: The term of the sole-source concession contract will commence (if awarded) no earlier than sixty (60) days from the publication of this notice, but the National Park Service intends for the term to begin March 1, 2022 (estimated) and end December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Kurt Rausch, Program Chief, Commercial Services Program, National Park Service, 1849 C Street NW, Mail Stop 2410, Washington, DC 20240; Telephone: 202–513–7156.

SUPPLEMENTARY INFORMATION: Pursuant to 36 CFR 51.25, the Director of the National Park Service (Service) may award a concession contract non-competitively upon a determination that extraordinary circumstances exist under which compelling and equitable considerations require the award of the concession contract to a particular qualified person in the public interest and that such an award is otherwise consistent with the requirements of part 51. Contracts that are awarded non-competitively under this authority are commonly referred to as ''sole-source'' contracts. The Service has determined that the proposed award of a sole-source contract to DNC Parks and Resorts at Yellowstone, LLC is necessary based on the following information.

The extraordinary circumstances in this instance include delays caused by the COVID–19 pandemic and the required updates to the YELL002 prospectus as a result of the pandemic's socio-economic impacts, as such impacts affected the assumptions developed for the prospectus to such an extent that the Service could not release the prospectus in July 2020 as originally planned. Additionally, the Service has exhausted the time allowed for temporary contracts authorized under 36 CFR 51.24, and does not have sufficient time to update the assumptions and requirements for a new prospectus, solicit and evaluate proposals, provide the 60-day notice to Congress, and competitively award a new contract before the expiration of the temporary contract on February 28, 2022.

The Service has determined that DNC Parks and Resorts at Yellowstone, LLC is a ''qualified person'' as defined by 36 CFR 51.3, and has determined that compelling and equitable considerations exist as only DNC Parks and Resorts at Yellowstone, LLC, having provided the visitor services since 2002 and having already made the investments necessary to provide the operations, is positioned to provide the visitor services without having potentially severe consequences to visitors to the Park.

The Service has determined that a sole-source concession contract is in the public interest because it is the authorization most likely to avoid interruption of visitor services and provide for the continued maintenance of government-owned facilities.

This is not a request for proposals. The publication of this notice reflects the intent of the Service but does not bind the Service to award the sole-source contract. Should the Service award the sole-source contract, the NPS will ensure such award is otherwise consistent with the requirements of part 51.

Justin Unger,

Associate Director, Business Services.

[FR Doc. 2022–00656 Filed 1–18–22; 8:45 am]

BILLING CODE 4312–53–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 221S180110; S2D2S SS08011000 SX064A000 22XS501520; OMB Control Number 1029–0120]

Agency Information Collection Activities; Nomination and Request for Payment Form for OSMRE's National Technical Training Courses

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before February 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0120 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 30, 2021 (86 FR 54236). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. 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; and

(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. 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: The form is used to identify and evaluate the training courses requested by students to enhance their job performance, to calculate the number of classes and instructors needed to complete OSMRE's technical training mission, and to estimate costs to the training program.

Title of Collection: Nomination and Request for Payment Form for OSMRE's National Technical Training Courses.

OMB Control Number: 1029–0120.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 800.

Total Estimated Number of Annual Responses: 800.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 67.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: $0.

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.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Division of Regulatory Support.

[FR Doc. 2022–00961 Filed 1–18–22; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 221S180110; S2D2S SS08011000 SX064A000 22XS501520; OMB Control Number 1029–0087]

Agency Information Collection Activities; State Regulatory Authority: Abandoned Mine Land Problem Area Description Form

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before February 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0087 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 15, 2021 (86 FR 51377). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. 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; and

(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. 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: The problem area description (PAD) form is used to update the Office of Surface Mining Reclamation and Enforcement's electronic inventory of abandoned mine lands (e-AMLIS). From this inventory, the most serious problem areas are selected for reclamation through the

apportionment of funds to States and Indian tribes.

Title of Collection: Abandoned Mine Land Problem Area Description Form.

OMB Control Number: 1029–0087.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 27.

Total Estimated Number of Annual Responses: 1,710.

Estimated Completion Time per Response: Varies from 1.5 hours to 8 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 4,580.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: $0.

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.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Division of Regulatory Support.

[FR Doc. 2022–00959 Filed 1–18–22; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–587]

Distributional Effects of Trade and Trade Policy on U.S. Workers

AGENCY: United States International Trade Commission.

ACTION: Notice of scheduling of roundtables, a symposium, and a hearing in connection with the investigation.

SUMMARY: The Commission has established a schedule and procedure, set forth below, for conducting roundtables, an academic symposium, and a hearing in connection with this investigation. The Commission will hold seven roundtable discussions between March 1 and April 1, 2022, an academic symposium on April 5–6, 2022, and a hearing on April 19, 2022. The roundtables, academic symposium, and hearing will focus on the potential distributional effects of goods and services trade and trade policy on U.S. workers by skill, wage and salary level, gender, race/ethnicity, age, and income level, especially as they affect underrepresented and underserved communities. The roundtables and hearing will afford an opportunity for interested persons to present information and views relating to the investigation, and the academic symposium will afford an opportunity for researchers and data experts to present work relevant to the investigation. The Commission instituted the investigation under section 332(g) of the Tariff Act of 1930 following receipt, on October 14, 2021, of a request from the U.S. Trade Representative.

DATES:

Commission events:

March 1: Roundtable on Race and Ethnicity I (virtual)

March 8: Impacts on Underserved Communities (in-person/virtual hybrid; from Fresno, CA)

March 10: Roundtable on Race and Ethnicity II (virtual)

March 14: Roundtable on Gender and Orientation (virtual)

March 22: Roundtable on Disability, Age, and Education (virtual)

March 30: Impacts on Underserved Communities (in-person/virtual hybrid; from Detroit, MI)

April 1: Roundtable on Local Economic Impacts on Underserved Communities (virtual)

April 5–6 Academic Symposium (virtual)

April 19: Hearing (virtual)

Filing deadlines relating to the roundtables:

February 15: Deadline for filing requests to appear at Roundtable on Race and Ethnicity I

February 22: Deadline for filing requests to appear at Roundtable on Impacts on Underserved Communities—Fresno, CA

February 24: Deadline for filing requests to appear at Roundtable on Race and Ethnicity II

February 28: Deadline for filing requests to appear at Roundtable on Gender and Orientation

March 8: Deadline for filing requests to appear at Roundtable on Disability, Age, and Education

March 16: Deadline for filing requests to appear at Roundtable on Impacts on Underserved Communities—Detroit, MI

March 18: Deadline for filing requests to appear at Roundtable on Local Economic Impacts on Underserved Communities

Filing deadlines relating to the academic symposium:

February 11: Deadline for submitting requests to appear and a copy of abstract and CV

March 1: Deadline for submitting papers

Filing deadlines relating to the hearing:

April 1: Deadline for filing requests to appear

April 5: Deadline for filing prehearing briefs and statements

April 12: Deadline for filing electronic copies of oral hearing statements

May 6: Deadline for filing posthearing briefs and statements

May 17: Deadline for filing all other written submissions

ADDRESSES: All Commission offices are in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. Due to the COVID 19 pandemic, the Commission's building is currently closed to the public. Once the building reopens, 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.

FOR FURTHER INFORMATION CONTACT: Co-Project Leader Jennifer Powell (202–205–3450 or *jennifer.powell@usitc.gov*), Co-Project Leader Stephanie Fortune-Taylor (202–205–2749 or *stephanie.fortune-taylor@usitc.gov*) or Deputy Project Leader Sarah Scott (202–708–1397 or *sarah.scott@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Jennifer Andberg, Office of External Relations (202–205–3404 or *jennifer.andberg@usitc.gov*).

The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* General information concerning the Commission may be obtained by accessing its internet address (*https://www.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.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 23, 2021, and published notice of its investigation in the **Federal Register** on November 30, 2021 (86 FR 67970). As requested by the USTR, the Commission will, in its report, catalogue information on the distributional effects of trade and trade policy on workers in underrepresented and underserved

communities. The Commission will gather information through multiple means, including:

(1) Roundtable discussions among representatives of underrepresented and underserved communities that have been identified in the Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985, January 20, 2021), as well as think tanks, academics and researchers, unions, State and local governments, non-Federal governmental entities, civil society experts, community-based stakeholders, such as minority-owned businesses, business incubators, Historically Black Colleges and Universities (HBCUs), Hispanic Serving Institutions (HSIs), Tribal Colleges and Universities (TCUs), other minority serving institutions (MSIs), and local and national civil rights organizations; underrepresented and underserved communities as listed in the Executive Order include Black, Latino, 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 in specific age, skill, or income groups; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality;

(2) an academic symposium focused on academic or similar research on the distributional effects of trade and trade policy on underrepresented and underserved communities, including results of existing analysis, evaluation of methodologies, the use of public and restricted data in current analysis, identifying gaps in data and/or in the economic literature, and proposed analysis that could be done with restricted data; and

(3) a hearing open to any individual wishing to present views in accordance with the investigation.

As the roundtables, symposium and hearing presentations are open to the public, persons participating should not include confidential business information (CBI) in any written submissions or presentations intended for use in the roundtables and symposium and in their oral presentations at the hearing.

Roundtables: The Commission will hold multiple roundtables for the purpose of seeking information and views from representatives of underrepresented and underserved communities on the distributional effects of trade and trade policy on U.S. workers by skill, wage and salary level, gender, race/ethnicity, age, and income level. Each roundtable will have a theme (designated as specified in the **DATES** section of this notice); however, any person is welcome to present views in accordance with the investigation at these events, regardless of roundtable theme.

- The virtual roundtables will be open to the public and will be held via an online videoconferencing platform, beginning at 1 p.m. Eastern Time on the dates specified in the **DATES** section of this notice.
- In-person roundtables will be held in Fresno, California and Detroit, Michigan beginning at 1 p.m. local time on the dates specified in the **DATES** section of this notice. These in-person roundtables will be conducted in a hybrid format, thus allowing in-person and virtual participation by registrants and virtual attendance by the public. In-person roundtables may transition to an entirely virtual format depending on public health developments, and updates regarding the format of these roundtables will be posted on the investigation website.

All of the roundtables will be recorded and transcribed. Those wishing to attend or participate in a roundtable should register by 5:15 p.m. EST on the day specified in the **DATES** section above by emailing *DE@usitc.gov* or calling (202) 536–9960. Attendees and participants will receive further information upon registration. In addition, details about individual roundtables will be posted at the investigation website. Interested parties should check the investigation website periodically for updates.

Symposium: The Commission will hold the public academic symposium via an online videoconferencing platform, beginning at 9:00 a.m. EST on April 5–6, 2022. Persons interested either in presenting work (published or ongoing) or serving on a panel discussion at the symposium should submit an abstract and curriculum vitae (CV) by emailing *DE@usitc.gov*. The abstract should be a document of approximately one page in length that includes the presenter's name, affiliation, email contact information, and job title. The abstract should also provide a summary of the presenter's original academic work(s) related to distributional effects, as described in the Background section.

Requests to present work or serve on a panel at the academic symposium should be emailed or submitted by 5:15 p.m. on February 11, 2022. Following the February 11th submission of abstracts and CVs, potential participants should submit papers and presentations by 5:15 on March 1 by emailing *DE@usitc.gov.*

Hearing: A public hearing in connection with this investigation will be held via an online videoconferencing platform, beginning at 9:30 a.m. Eastern Time on April 19, 2022. Public testimony at this hearing should focus on the distributional effects described above. Information about how to participate in or view the hearing will be posted on the Commission's website at (*https://usitc.gov/research_and_analysis/what_we_are_working_on.htm*). Once on that web page, scroll down to the entry for Investigation No. 332–587, *Distributional Effects of Trade and Trade Policy on U.S. Workers,* and click on the link to ''Hearing Instructions.'' Interested parties should check the Commission's website periodically for updates. Information about the hearing will also be posted on the investigation specific website (*https://www.usitc.gov/research_and_analysis/ongoing/distributional_effects_332*).

Requests to appear at the hearing should be filed with the Secretary to the Commission no later than 5:15 p.m., April 1, 2022, in accordance with the requirements in the ''Written Submissions'' section below. All prehearing briefs and statements should be filed not later than 5:15 p.m., April 5, 2022. To facilitate the hearing, including the preparation of an accurate written public transcript of the hearing, oral testimony to be presented at the hearing must be submitted to the Commission electronically no later than noon, April 12, 2022. All posthearing briefs and statements should be filed not later than 5:15 p.m., May 6, 2022. Posthearing briefs and statements should address matters raised at the hearing. For a description of the different types of written briefs and statements, see the ''Definitions'' section below.

If, as of the close of business on April 1, 2022, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after April 4, 2022, for information concerning whether the hearing will be held.

Written submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., May 17, 2022. All written submissions must conform to the

provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at 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. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802), or consult the Commission's Handbook on Filing Procedures.

Definitions of types of documents that may be filed; Requirements: In addition to requests to appear at the hearing, this notice provides for the possible filing of four types of documents: Prehearing briefs, oral hearing statements, posthearing briefs, and other written submissions.

(1) *Prehearing briefs* refers to written materials relevant to the investigation and submitted in advance of the hearing, and includes written views on matters that are the subject of the investigation, supporting materials, and any other written materials that you consider will help the Commission in understanding your views. You should file a prehearing brief particularly if you plan to testify at the hearing on behalf of an industry group, company, or other organization, and wish to provide detailed views or information that will support or supplement your testimony.

(2) *Oral hearing statements (testimony)* refers to the actual oral statement that you intend to present at the hearing. Do not include any confidential business information in that statement. If you plan to testify, you must file a copy of your oral statement by the date specified in this notice. This statement will allow Commissioners to understand your position in advance of the hearing and will also assist the court reporter in preparing an accurate transcript of the hearing (*e.g.,* names spelled correctly).

(3) *Posthearing briefs* refers to submissions filed after the hearing by persons who appeared at the hearing. Such briefs: (a) Should be limited to matters that arose during the hearing, (b) should respond to any Commissioner and staff questions addressed to you at the hearing, (c) should clarify, amplify, or correct any statements you made at the hearing, and (d) may, at your option, address or rebut statements made by other participants in the hearing.

(4) *Other written submissions* refer to any other written submissions that interested persons wish to make, regardless of whether they appeared at the hearing, and may include new information or updates of information previously provided.

In accordance with the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8) the document must identify on its cover (1) the investigation number and title and the type of document filed (*i.e.,* prehearing brief, oral statement of (name), posthearing brief, or written submission), (2) the name and signature of the person filing it, (3) the name of the organization that the submission is filed on behalf of, and (4) whether it contains confidential business information (CBI). If it contains CBI, it must comply with the marking and other requirements set out below in this notice relating to CBI. Submitters of written documents (other than oral hearing statements) are encouraged to include a short summary of their position or interest at the beginning of the document, and a table of contents when the document addresses multiple issues.

Confidential business information: Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

As requested by the USTR, the Commission will not include any confidential business information in the report it sends to the USTR. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a way that would reveal the operations of the firm supplying the information.

Summaries of written submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission on or before May 17, 2022, and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the report'' at the top of the page. The summary may not exceed 500 words and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the written submission can be found.

By order of the Commission.

Issued: January 12, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–00912 Filed 1–18–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–678 and 731–TA–1584 (Preliminary)]

Barium Chloride From India; Institution of Countervailing Duty and Antidumping Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase countervailing duty and antidumping duty investigation Nos. 701–TA–678 and 731–TA–1584 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that 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 barium chloride from India, provided for in subheading 2827.39.45 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair

value and alleged to be subsidized by the Government of India. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in countervailing duty and antidumping duty investigations in 45 days, or in this case by February 28, 2022. The Commission's views must be transmitted to Commerce within five business days thereafter, or by March 7, 2022.

DATES: January 12, 2022.

FOR FURTHER INFORMATION CONTACT: Alejandro Orozco (202–205–3177), 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:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on January 12, 2022, by Chemical Products Corporation, Cartersville, Georgia.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission countervailing duty and antidumping duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is conducting the staff conference through video conferencing on February 2, 2022. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before January 31, 2022. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

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.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before February 7, 2022, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on February 1, 2022. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the 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.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: January 12, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–00911 Filed 1–18–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Networking Devices, Computers, and Components Thereof and Systems Containing the Same, DN 3593;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Proven Network LLC on January 13, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain networking devices, computers, and components thereof and systems containing the same. The complainant names as respondent: NetApp, Inc. of San Jose, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3593'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] 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. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: January 13, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–00936 Filed 1–18–22; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Tel-Pharmacy; Decision and Order

On August 3, 2017, the then Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Tel-Pharmacy (hereinafter, Applicant) of Coconut Creek, Florida. OSC, at 1. The OSC proposed the denial of Applicant's application for DEA Certificate of Registration No. W16006664A. It alleged that Applicant ''does not have authority to operate a pharmacy in Florida, the state for which it seeks a [DEA registration].'' *Id.* (citing 21 U.S.C. 823(f)). Specifically, the OSC alleged that Applicant's Florida pharmacy permit expired on February 28, 2017, and was not renewed. *Id.* at 2.

The OSC notified Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated December 6, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the DEA's Miami Field Division stated that on August 4, 2017, a Special Agent and Task Force Officer from DEA's Miami Field Division hand-delivered a copy of the OSC to Applicant's agent at the agent's residence. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 1, at 1–2; *see also* RFAAX 1, Appendix (hereinafter, App.) B.

The Government forwarded its RFAA, along with the evidentiary record, to this office on December 8, 2021. In its RFAA, the Government represents that ''neither [Applicant] nor any attorney representing [Applicant] has requested a hearing'' nor ''has [Applicant] nor any attorney for [Applicant] submitted a written statement.'' RFAA, at 2. The Government ''seeks to deny [Applicant's] application for a [DEA registration] because [Applicant] lacks authority to handle controlled substances in [Florida], the state in which it seeks registration with DEA.'' *Id.* at 1. Accordingly, the Government requests that the Administrator deny Applicant's application. *Id.* at 5.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Applicant on August 4, 2017. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Applicant, nor anyone purporting to represent the Applicant, requested a hearing, submitted a written statement while waiving Applicant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Applicant's Application for DEA Registration

On or about January 27, 2016, Applicant submitted an application for a DEA Certificate of Registration as a retail pharmacy in Schedules II through V with a proposed registered address at 5489 Wiles Rd. 302, Coconut Creek, FL 33073. RFAAX 1, App. A, at 1. Applicant's application was assigned Control No. W16006664A.[1] *Id.*

The Status of Applicant's State License

In her Declaration, the DI stated that as of December 6, 2021, Applicant's state license was listed as ''null and void'' on the Florida Department of Health website. RFAAX 1, at 2; *see also* RFAAX 1, App. C. According to the Florida Department of Health's online records, of which I take official notice, Applicant's state pharmacy registration PH29813 is ''null and void.'' [2] Florida Department of Health's License Verification, *https://mqa-internet.doh.state.fl.us/MQASearchServices/Home* (last visited date of signature of this Order).

Accordingly, I find that Applicant is not currently licensed to engage in the practice of pharmacy in Florida, the state in which Applicant applied for registration with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had [its] State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a pharmacy . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g.,*

[1] In spite of Applicant's discontinuance of business, its application remains pending and I will continue to assess the application under 21 U.S.C. 823. *See Lawrence E. Stewart, M.D.,* 86 FR 15,257 (2021).

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Applicant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

James L. Hooper, 76 FR 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR 27,617.

According to Florida statute, ''It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy: (a) Which is not registered under the provisions of this chapter.'' Fla. Stat. Ann. 465.015(1). Further, ''the practice of the profession of pharmacy'' definition ''includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug[3] . . . .'' Fla. Stat. Ann. 465.003(13) (West, 2021).

Here, the undisputed evidence in the record is that Applicant currently lacks authority to operate a pharmacy in Florida. As already discussed, a pharmacy must be a licensed to dispense a medicinal drug, including a controlled substance, in Florida. Thus, because Applicant lacks authority to practice pharmacy in Florida and, therefore, is not authorized to dispense controlled substances in Florida, Applicant is not eligible to receive a DEA registration. Accordingly, I will order that Applicant's application for a DEA registration be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby order that the pending application for a Certificate of Registration, Control Number W16006664A, submitted by Tel-Pharmacy, is denied, as well as any other pending application of Tel-Pharmacy for additional registration in Florida. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–00956 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–09–P

[3] ''Medicinal Drugs'' or ''Drugs'' means ''those substances or preparations commonly known as 'prescription' or 'legend' drugs which are required by federal or state law to be dispensed only on a prescription . . . .'' Fla. Stat. Ann. 465.003(8).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–08]

AARRIC, Inc. d/b/a at Cost RX; Decision and Order

On January 3, 2020, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to AARRIC, Inc. d/b/a AT COST RX (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FA2125640 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from November 16–20, 2020, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference.*[A] On April 7, 2021, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On

*[A] [This footnote has been relocated from RD n.5.] At all times prior to and during the hearing, the Respondent was represented by multiple, able counsel. The Respondent's (then) counsels raised no issue during the proceedings or in the Respondent's closing brief regarding the fairness of the proceedings. The day after its closing brief was filed, the Respondent sought to discharge its lawyers and opted to have itself represented by its (non-lawyer) owner. ALJ Ex. 56. Acting as a non-attorney representative (*see* 21 CFR 1316.50), the Respondent's owner moved to disqualify the Government's expert and to recuse me [the Chief ALJ]. ALJ Exs. 57, 58, 61. These motions have been disposed of in separate orders issued contemporaneously with this recommended decision. ALJ Exs. 67, 68. A joint motion to be excused from further representation of the Respondent (ALJ Ex. 60) filed by his lawyers (at the request of the tribunal) was granted for the reasons stated therein. ALJ Ex. 62.

[I agree with the Chief ALJ's procedural rulings in this case, including his dismissal of Respondent's two recusal motions. In these motions, Respondent argued that the Chief ALJ ''den[ied] Respondent [the] right to a fair trial'' by ''creat[ing] an atmosphere of prejudice and lack of impartiality.'' ALJ Ex. 57, at 3. Respondent further argued that the Chief ALJ ''morphed [the Government's case] into a plausible case'' by ''w[earing] the hat of the Government's lawyer during most of the witness examination.'' *Id.* at 2. Respondent's motions reference portions of the record where the Chief ALJ assisted the Government in authenticating documents and questioning its witnesses. Although Respondent acknowledged that ALJs are permitted to question witnesses, Respondent argues that the Chief ALJ used his questioning authority to buttress the Government's case and ''patch[ ] up areas where there were obvious gaps in the Government's case,'' while not ''provid[ing] the same helping hand to Respondent when Respondent was attempting to authenticate documents that Respondent believes were critical to its defense. *Id.* at 5, 10. Additionally, Respondent alleged that it was inappropriate for the Chief ALJ to ask Respondent's representative, Dr. Howard, whether he agreed with certain testimony by Respondent's expert, because it ''placed . . . Dr. Howard in an awkward position to have to incriminate his own expert just to appease the ALJ.'' *Id.* at 26, 30.

I find that Respondent's recusal motions are without merit. As the Chief ALJ stated in his neutral and carefully-reasoned dismissal order, Respondent—the proponent of the recusal motion—has the burden of demonstrating that the Chief ALJ exhibited a ''deep-seated favoritism or antagonism that would make fair judgment impossible.'' Order Denying the Respondent's Recusal Motions, at 6. Respondent did not identify any evidence of favoritism or antagonism, much less the type of deep-seated favoritism or antagonism that would make fair judgment impossible. Rather, Respondent identified instances where the Chief ALJ was exercising his discretionary authority to regulate the hearing, by asking clarifying questions of counsel and witnesses and issuing evidentiary rulings. *See* Order, at 7 (citing 5 U.S.C. 556(c)(5); 21 CFR 1316.52(e)). Courts have uniformly held that judicial rulings issued during the course of litigation rarely constitute evidence of cognizable bias. *Id.* (citing *Liteky* v. *United States,* 510 U.S. 540, 555 (1994), *Hamm* v. *Members of Bd. of Regents,* 708 F.2d 647, 651 (11th Cir. 1983), *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,958–59 (2010)). Additionally, as the Chief ALJ highlighted in his dismissal order, the Chief ALJ frequently clarified the record for Respondent's benefit and overwhelmingly issued evidentiary rulings in Respondent's favor. *Id.* at 8–9. Furthermore, Respondent's recusal motions were untimely, which is an independent basis for their dismissal. *Id.* at 7, 15–16.

Beyond the substantive and procedural defects of Respondent's recusal motions, the motions convey a contemptuous tone towards the Chief ALJ, which supports my decision that Respondent's registration is inconsistent with the public interest. Respondent was particularly outraged that the Chief ALJ questioned Respondent's representative about whether he agreed with the Respondent's expert's expressions of hostility towards DEA as a regulator. Based on Respondent's attitude towards DEA and the Chief ALJ, I find it unlikely that Respondent would modify its behavior and become a law-abiding, cooperative registrant. Certainly, Respondent's focus on repudiating the Chief ALJ rather than acknowledging its own misconduct shows that it falls far short of the ''true remorse'' that is required when a registrant has committed acts that are inconsistent with the public interest. *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011).

For the same reasons stated above, I find that Respondent's Exceptions to ALJ's Denial of Respondent's Motions for Recusal and Request for Expedited Ruling on the Order Denying Recusal are without merit. ALJ Ex. 69 (dated April 27, 2021).]

December 15, 2020, the Government and Respondent filed exceptions to the Recommended Decision (hereinafter, Gov Exceptions and Resp Exceptions, respectively). Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the ALJ's Recommended Decision with minor modifications, as noted herein. I have addressed each of Respondent's Exceptions and I issue my final Order in this case following the Recommended Decision.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *B 1 2 3

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The Government alleges that the Respondent Pharmacy's COR should be revoked because on numerous occasions between February 2018 and September 2019, it repeatedly dispensed prescriptions to ten patients (collectively, the Ten Patients) [4] without addressing or resolving factual *indicia* (*i.e.,* ''red flags'') of potential drug diversion and in contravention of its corresponding responsibility to ensure the prescriptions were issued for a legitimate medical purpose. ALJ Ex. 1 at 2.

The Evidence

The Stipulations

The parties entered into factual stipulations prior to the litigation of this matter, which were accepted by the tribunal.[5] By virtue of those stipulations, the following factual matters are deemed conclusively established in this case:

1. The Respondent is registered with DEA to handle controlled substances in Schedules II through V under DEA COR No. FA2125640 at 16970 San Carlos Boulevard, Suite 110, Fort Myers, Florida 33908.

2. DEA COR No. FA2125640 will expire by its own terms on June 30, 2022.

3. DEA lists Adderall (amphetamine–dextroamphetamine mixture) as a Schedule II controlled substance under 21 CFR 1308.12(d)(1).

4. DEA lists Ambien (zolpidem tartrate) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(57).[6]

5. DEA lists Ativan (lorazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(32).

6. DEA lists hydromorphone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vii).

7. DEA lists Klonopin (clonazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(12).

8. DEA lists methadone as a Schedule II controlled substance under 21 CFR 1308.12(c)(15).

9. DEA lists MS Contin (morphine sulfate extended release) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(ix).

10. DEA lists Norco (hydrocodone–acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vi).

11. DEA lists oxycodone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiv).

12. DEA lists Percocet (oxycodone–acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiv).

13. DEA lists Restoril (temazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(53).

14. DEA lists Soma (carisoprodol) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(7).

15. DEA lists Valium (diazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(17).

16. DEA lists Xanax (alprazolam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(2).

17. Between February 19, 2018, and at least September 2, 2019, the Respondent filled at least 21 prescriptions for *Patient JA* for 90–120 units of hydromorphone 8 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug dispensed	Prescription No.
2/19/2018	112 units of hydromorphone 8 mg	535081
3/19/2018	112 units of hydromorphone 8 mg	535597
4/16/2018	120 units of hydromorphone 8 mg	536108
5/14/2018	120 units of hydromorphone 8 mg	536635
6/11/2018	120 units of hydromorphone 8 mg	537027
7/10/2018	120 units of hydromorphone 8 mg	537292
8/7/2018	120 units of hydromorphone 8 mg	537539
9/4/2018	120 units of hydromorphone 8 mg	537922
10/2/2018	120 units of hydromorphone 8 mg	538321
10/30/2018	120 units of hydromorphone 8 mg	538758
11/26/2018	120 units of hydromorphone 8 mg	539235
12/21/2018	120 units of hydromorphone 8 mg	539671
1/21/2019	120 units of hydromorphone 8 mg	540097
2/18/2019	120 units of hydromorphone 8 mg	540569
3/18/2019	120 units of hydromorphone 8 mg	541028
4/15/2019	120 units of hydromorphone 8 mg	541503
5/13/2019	105 units of hydromorphone 8 mg	541983
6/10/2019	90 units of hydromorphone 8 mg	542444
7/8/2019	90 units of hydromorphone 8 mg	542892
8/5/2019	90 units of hydromorphone 8 mg	543372
9/2/2019	90 units of hydromorphone 8 mg	543802

*B I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] [Footnote relocated, *see infra* n. *M.]

[2] [Footnote relocated, *see supra* n.*A.]

[3] [Omitted for brevity.]

[4] In this recommended decision, initials have been substituted for the names of the Respondent's customer-patients to preserve their personally identifiable information. The Ten Patients include Patients JA, EA, SD, LH, DH, DK, JM, ST, JW, and CW.

[5] ALJ Ex. 38.

[6] Multiple incorrect citations set forth in the proposed stipulations propounded by the parties have been corrected in this RD to reflect the current regulatory designation.

18. Patient JA paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

19. Between September 19, 2018, and at least September 16, 2019, the Respondent filled at least 42 prescriptions for *Patient EA* for 28 units of MS Contin 30 mg, 120 units of oxycodone 30 mg, and 30 units of Xanax 1 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
9/19/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538184–538186
10/17/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538570–538572
11/15/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539086–539088
12/13/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539524–539525; 539527
1/9/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539931–539932; 539935
2/5/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540377–540378; 540381
3/4/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540812–540814
4/1/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541310–541311; 541314
4/24/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541726–541728
5/22/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542191; 542193–542194
6/25/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542751–542753
7/24/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	543220–543221; 543223
8/20/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	543644–543646
9/16/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	544051–544053

20. Patient EA paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

21. Between February 20, 2018, and at least September 4, 2019, the Respondent filled at least 56 prescriptions for *Patient SD* for 21–30 units of MS Contin 30 mg, 60 units of MS Contin 60 mg, 92–135 units of oxycodone 30 mg, 30 units of Xanax 0.5 mg, and 30 units of Xanax 1 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/20/2018	60 units of MS Contin 60 mg; 135 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	535123–535125
3/21/2018	60 units of MS Contin 60 mg; 135 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	535637–535638; 535643
4/17/2018	60 units of MS Contin 60 mg; 135 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	536133–536135
5/15/2018	30 units of Xanax 1 mg	536670
8/9/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 0.5 mg	537591–537592; 537606
9/7/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 0.5 mg	538017–538019
10/4/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538376–538377; 538379
10/31/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538811–538813
11/7/2018	92 units of oxycodone 30 mg	538974
11/27/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539262; 539264–539265
12/24/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539680–539682
1/22/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540132–540134
2/19/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540597–540598; 540600
3/18/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541054; 541056–541057
4/15/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541524; 541526–541527
5/13/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542001–542003
6/11/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542498–542500
7/8/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542917–542919
8/6/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	543410–543412
9/4/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 0.5 mg	543858–543860

22. Patient SD paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent on or after April 16, 2018.

23. Between March 6, 2018, and at least September 11, 2019, the Respondent filled at least 34 prescriptions for *Patient LH* for 28–60 units of MS Contin 30 mg and 120–140 units of oxycodone 30 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
3/6/2018	60 units of MS Contin 30 mg; and 140 units of oxycodone 30 mg	535451–535452
4/3/2018	60 units of MS Contin 30 mg; and 140 units of oxycodone 30 mg	535887–535888
5/8/2018	60 units of MS Contin 30 mg; and 140 units of oxycodone 30 mg	536542–536543
8/28/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	537859–537860
10/10/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	538473–538474
11/7/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	538955–538956
12/5/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	539397–539398
1/3/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	539816–539817
1/30/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	540243–540244
2/27/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	540720–540721
3/27/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	541246–541247
4/24/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	541706–541707

Fill date	Drug(s) dispensed	Prescription Nos.
5/22/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	542196–542197
6/19/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	542646–542647
7/17/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	543112–543113
8/14/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	543557–543558
9/11/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	543979; 543982

24. Patient LH paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

25. Between March 8, 2018, and at least September 11, 2019, the Respondent filled at least 59 prescriptions for *Patient DH* for 60 units of MS Contin 30 mg, 120 units of hydromorphone 8 mg, and 60 units of Xanax 2 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
3/8/2018	60 units of MS Contin 30 mg	535478
3/13/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	535525–535526
4/10/2018	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	536047; 536050; 536053
5/8/2018	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	536566–536567; 536571
6/5/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	536993–536994
6/15/2018	60 units of MS Contin 30 mg	537081
7/4/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	537254; 537257
7/13/2018	60 units of MS Contin 30 mg	537339
7/31/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	537486; 537489
8/28/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	537853; 537857
8/31/2018	60 units of MS Contin 30 mg	537906
9/25/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538255; 538258
10/5/2018	60 units of MS Contin 30 mg	538386
10/23/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538663; 538666
11/2/2018	60 units of MS Contin 30 mg	538879
11/20/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	539162; 539165
12/3/2018	60 units of MS Contin 30 mg	539350
12/18/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	539596; 539599
12/31/2018	60 units of MS Contin 30 mg	539743
1/15/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	540031; 540035
1/28/2019	60 units of MS Contin 30 mg	540191
2/12/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	540467; 540473
2/25/2019	60 units of MS Contin 30 mg	540670
3/11/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	540938–540939
3/25/2019	60 units of MS Contin 30 mg	541179
4/8/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	541428–541429
4/22/2019	60 units of MS Contin 30 mg	541661
5/6/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	541914–541915
5/20/2019	60 units of MS Contin 30 mg	542133
6/3/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	542349; 542358
6/17/2019	60 units of MS Contin 30 mg	542587
7/1/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	542839–542840
7/15/2019	60 units of MS Contin 30 mg	543059
7/29/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	543275–543276
8/12/2019	60 units of MS Contin 30 mg	543489
8/26/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	543703–543704
9/11/2019	60 units of MS Contin 30 mg	543975

26. Patient DH paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

27. Between February 16, 2018, and at least September 12, 2019, the Respondent filled at least 59 prescriptions for *Patient DK* for 60 units of MS Contin 30 mg, 60 units of MS Contin 60 mg, 90–120 units of hydromorphone 8 mg, 90 units of Xanax 0.5 mg, 60 units of Xanax 1 mg, and 35–60 units of Soma 350 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/16/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; 60 units of Xanax 1 mg; and 60 units of Soma 350 mg.	535071–535074
3/14/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 35 units of Soma 350 mg	535552; 535557–535558
3/16/2018	60 units of Xanax 1 mg	535590
5/16/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	536704; 536707–536708
5/18/2018	60 units of Soma 350 mg	536732
6/13/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Soma 350 mg	537054–537056
6/20/2018	60 units of Xanax 1 mg	537145

Fill date	Drug(s) dispensed	Prescription Nos.
7/11/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	537307–537309
8/8/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	537565–537566; 537568
9/18/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	538219–538221
10/17/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	538548–538550
11/16/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	539113; 539115–539116
12/14/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	539557–539558; 539560
1/11/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	539990–539991; 539993
2/13/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	540509–540510; 540512
3/12/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	540971; 540977–540978
4/11/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	541496; 541498; 541500
5/9/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	541975–541977
6/6/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	542430–542431; 542433
7/5/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	542882–542883; 542889
8/13/2019	60 units of MS Contin 30 mg	543528
8/30/2019	90 units of hydromorphone 8 mg; and 90 units of Xanax 0.5 mg	543798; 543800
9/12/2019	60 units of MS Contin 30 mg	544003

28. Patient DK paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

29. Between February 28, 2018, and at least September 17, 2019, the Respondent filled at least 78 prescriptions for *Patient JM* for 60 units of MS Contin 30 mg, 120 units of hydromorphone 8 mg, 60 units of Restoril 15 mg, 30 units of Restoril 30 mg, and 60 units of Xanax 2 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/28/2018	30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	535267; 535269
3/5/2018	120 units of hydromorphone 8 mg	535393
3/9/2018	60 units of MS Contin 30 mg	535492
3/28/2018	30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	535799–535800
4/2/2018	120 units of hydromorphone 8 mg	535842
4/9/2018	60 units of MS Contin 30 mg	536038
5/1/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	536422; 536424–536425
5/8/2018	60 units of MS Contin 30 mg	536574
5/29/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	536909–536911
6/4/2018	60 units of MS Contin 30 mg	536967
6/26/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	537182–537183; 537189
7/5/2018	60 units of MS Contin 30 mg	537266
7/24/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	537451; 537452; 537455
8/1/2018	60 units of MS Contin 30 mg	537508
8/21/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	537773; 537778–537779
8/31/2018	60 units of MS Contin 30 mg	537909
9/18/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538160; 538162
9/24/2018	30 units of Restoril 30 mg	538235
9/28/2018	60 units of MS Contin 30 mg	538302
10/17/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538541; 538543
10/26/2018	60 units of MS Contin 30 mg; and 30 units of Restoril 30 mg	538728; 538730
11/13/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	539024; 539026
11/26/2018	60 units of MS Contin 30 mg; and 30 units of Restoril 30 mg	539245; 539247
1/9/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg.	539924–539925; 539927–539928
2/6/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg.	540415; 540417; 540419–540420
3/7/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 60 units of Restoril 15 mg; and 60 units of Xanax 2 mg.	540900–540903
4/3/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 60 units of Restoril 15 mg; and 60 units of Xanax 2 mg.	541355–541358
4/30/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	541815–541816
5/3/2019	60 units of MS Contin 30 mg	541878
5/28/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	542248–542249; 542252
5/30/2019	60 units of MS Contin 30 mg	542315
6/25/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	542726; 542729
6/27/2019	60 units of MS Contin 30 mg	542801
7/23/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	543189–543190; 543194
7/25/2019	60 units of MS Contin 30 mg	543238
8/20/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	543628–543630
8/23/2019	60 units of MS Contin 30 mg	543696
9/17/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	544074–544076

30. Patient JM paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

31. Between March 7, 2018, and at least August 21, 2019, the Respondent filled at least 40 prescriptions for *Patient ST* for 60 units of MS Contin 60 mg and 150 units of oxycodone 30 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
3/7/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	535465–535466
4/4/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	535928–535929
5/2/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	536448–536449
5/30/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	536925; 536934
6/27/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	537209–537210
7/25/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	537471–537472
8/22/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	537781–537782
9/19/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	538182–538183
10/17/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	538555–538556
11/14/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	539062–539063
12/12/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	539505–539506
1/9/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	539913–539914
2/6/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	540400–540401
3/7/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	540894–540895
4/3/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	541363–541364
5/1/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	541831–541832
5/29/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	542282–542283
6/26/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	542762–542763
7/24/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	543217–543218
8/21/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	543650–543651

32. Patient ST paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent on or after April 4, 2018.

33. Between April 19, 2018, and at least May 2, 2019, the Respondent filled at least 30 prescriptions for *Patient JW* for 28–90 units of methadone 10 mg, 112–120 units of oxycodone 30 mg, and 30 units of Xanax 1 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
4/19/2018	90 units of methadone 10 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	536190–536191; 536194
5/23/2018	90 units of methadone 10 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	536860–536862
8/29/2018	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	537877–537878; 537881
11/12/2018	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539000–539002
12/11/2018	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539482–539484
1/8/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539875; 539877–539878
2/6/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540394; 540397–540398
3/7/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540886–540888
4/3/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541369–541370; 541374
5/2/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541863–541865

34. Patient JW paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

35. Between February 26, 2018, and at least August 28, 2019, the Respondent filled at least 33 prescriptions for *Patient CW* for 30 units of methadone 5 mg, 30–60 units of methadone 10 mg, 90–120 units of hydromorphone 8 mg, 30 units of Xanax 0.5 mg, 30 units of Xanax 1 mg, and 90 units of Xanax 2 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/26/2018	90 units of hydromorphone 8 mg	535206
3/26/2018	90 units of hydromorphone 8 mg	535720
4/23/2018	90 units of hydromorphone 8 mg	536247
5/21/2018	90 units of hydromorphone 8 mg	536776
7/24/2018	60 units of methadone 10 mg; 120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	537446–537448
8/24/2018	30 units of methadone 5 mg	537818
9/25/2018	30 units of methadone 10 mg; 120 units of hydromorphone 8 mg; and 90 units of Xanax 2 mg	538259; 538261; 538266
10/23/2018	30 units of methadone 10 mg; and 120 units of hydromorphone 8 mg	538675–538676
10/24/2018	30 units of Xanax 1 mg	538714
11/19/2018	30 units of methadone 10 mg; and 120 units of hydromorphone 8 mg	539145–539146
11/20/2018	30 units of Xanax 0.5 mg	539154
12/17/2018	30 units of methadone 10 mg; and 120 units of hydromorphone 8 mg	539591–539592
1/15/2019	30 units of methadone 5 mg; and 120 units of hydromorphone 8 mg	540015–540016
2/19/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	540583; 540585
3/19/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	541065; 541069
4/16/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	541548–541549

Fill date	Drug(s) dispensed	Prescription Nos.
6/4/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	542374–542375
7/31/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	543329–543330
8/28/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	543773–543774

36. Patient CW paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

The Government's Case *[C]

In addition to its reliance on the agreed factual stipulations reached by the parties in this case, the Government presented its case through the testimony of a DEA Diversion Investigator and an expert pharmacy witness.

Diversion Investigator

The Government presented the testimony of a DEA Diversion Investigator (DI). DI testified that, as of the date of the hearing, he has been a DI for approximately three years and is currently stationed at the Miami field office. Tr. 19. The investigation that culminated in the present administrative charges was initiated by DI's predecessor, DI 2. Tr. 22. Upon DI 2's retirement from DEA, DI assumed responsibility as the lead DEA investigator on the case and inherited both open and closed evidence requests, as well as the balance of the investigative case file. Tr. 22–23. According to DI, the Respondent became the focus of DEA's attention after an on-site inspection by DEA in 2015. Tr. 24. DI's testimony was also used to authenticate a number of Government Exhibits, consisting of documents obtained during the course of the investigation. Tr. 31, 35, 38, 40–41, 46, 48–49, 62, 65, 67, 76, 79–80, 109–10, 364.

DI presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate. As a successor investigator, he demonstrated candor in teasing out which aspects of the investigation were initiated/controlled by him, and which aspects were inherited. Where he was unsure of an answer, he presented a good-faith effort but made no attempt to supply a convenient contrivance. The testimony of this witness, viewed *in toto,* was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

Dr. Tracey Schossow, Pharm.D.

The Government presented the expert testimony of Dr. Tracey Schossow. Dr. Schossow's *curriculum vitae* (CV) [7] reflects that she received a Doctorate in Pharmacy in 2001, has practiced,[8] managed, consulted, trained, and taught pharmacy for twenty-six years in a variety of settings, and even authored the pharmacy portion of a manual for a hospice company. Tr. 135, 155; Gov't Ex. 17. In fact, the witness testified that her introduction to the pharmacy profession commenced with work as a pharmacy technician in her father's independent pharmacy back in 1982. Tr. 136.

In the midst of a largely uneventful presentation, there arose a bizarre twist of events that bears special mention. During a cross-examination conducted by the Respondent's (then) counsel, Dr. Schossow [testified] that she was familiar with the composition of the Florida Board of Pharmacy, and volunteered that ''It's made up of pharmacists. I sat on the Board one time so—a long time ago.'' Tr. 455. Since neither Dr. Schossow's CV,[9] nor her direct testimony regarding her qualifications, reflected past employment as a Board member, [this testimony was unexpected. On cross examination, Respondent's counsel followed up on this issue with Dr. Schossow, and they had the following exchange:

Q: I understood you to say that you sat on the Board of Pharmacy for a period of time? Is that right?

A: When I first graduated from pharmacy school, yes. I was—this was a long time ago. I don't know if it was—I don't remember the position, exactly. It wasn't, like,—I wasn't the head of the Board, or anything like that. But I did sit on the Board in the meetings.

Q: Okay. And did you vote and participate in the process?

A: I participated in the process, but I didn't have any voting—I didn't do any voting.

Q: Okay. So, what you're talking about is, maybe, internship-type position with the board of pharmacy?

A: I don't recall the exact title of it. It was not an intern position. I was a licensed pharmacist at the time.

Q: All right. And so, this was, when? After you received your initial degree as a registered pharmacist, or during your Pharm D program?

A: No, it was after I received my initial pharmacy degree back in '94.

Tr. 546–47. Dr. Schossow then confirmed that she ''wasn't sitting on the board'' and ''didn't have a title like that,'' but she did participate. *Id.* at 547. She continued, ''It was a long time ago, so I do not recall the official, whatever I was doing at that time.'' *Id.* As discussed in more detail below, this testimony was inconsistent and confusing.

Dr. Schossow also testified that she could not recall particular sources that she reviewed prior to her testimony in this case, but stated that she is constantly reviewing a variety of information from legal sources, federal guidelines, as well as clinical data and studies to stay current on the applicable standard of care for Florida pharmacists.[10] Tr. 152–53, 163; *see also id.* at 193. Dr. Schossow also volunteered that she ''also had a lot of patients in the community arrested for opioid and other controlled substance fraud and abuse.'' [11] Tr. 137. The witness testified that she has also served as a pharmacy expert reviewer in federal agency cases involving controlled substances [12] and has been recognized as an expert witness on multiple occasions in administrative enforcement cases. Tr. 145–47. Dr. Schossow was tendered [13] and, over the Respondent's

*[C] Throughout the Chief ALJ's description of both the Government's Case and the Respondent's Case, I have made some minor adjustments to the wording where noted for brevity and for clarity and to reflect more of my style. I agree with the Chief ALJ on the astute points that he made and I have left in the content.

[7] Gov't Ex. 17.

[8] Dr. Schossow testified that she has practiced as a clinical pharmacist and a retail pharmacist. Tr. 145. In her words, ''a retail pharmacist does most of the actual dispensing of the medications into the bottles, versus a clinical pharmacist is more involved with the patient and the doctor, working more closely with them, usually offering recommendations on managing the patient.'' *Id.* The witness testified that she practiced retail pharmacy for about twelve years. *Id.*

[9] Gov't Ex. 17.

[10] The witness testified that the Florida requirement for continuing education is limited to one hour every two years. Tr. 197.

[11] This portion of the witness's testimony was objected to as irrelevant by the Respondent's counsel, and the tribunal subsequently sustained the objection. Thus, while no part of this statement will be considered to the detriment of the Respondent, it does present some potential insight into the mindset of the Government's expert. Its consideration is limited to that narrow point.

[12] Dr. Schossow testified that she has been compensated for her professional work as an expert, including by DEA in this case. Tr. 530. She also testified that although thus far her expert opinion has been exclusively sought by DEA, she would be willing to ''give [her] opinion to anybody who asks [her] regarding pharmacy.'' Tr. 162–63.

[13] Tr. 149.

objection, was accepted as an expert witness in the standard of care for Florida pharmacists and pharmacy practice in the State of Florida. Tr. 166–67.

According to Dr. Schossow, the applicable standard of care for dispensing controlled substances in Florida requires a pharmacist to evaluate every prescription presented by a patient.[14] Tr. 168–69. Dr. Schossow encapsulated her view of applicable statutes governing state corresponding responsibility in Florida as follows:

> [T]he responsibility of a [Florida] pharmacist is to ensure the safety and efficacy of the therapy for that person and also to protect that person in regards to safety for the patient and the community. It's very clear.

Tr. 171. Less helpfully, at another point in her testimony, the witness defined the applicable standard of care as ''[w]hat usually a normal pharmacist would do in a pharmacy or how they would practice the profession of pharmacy.'' Tr. 181; *see also id.* at 336.

According to the Government's expert, in evaluating a prescription, a Florida pharmacist is required to perform a drug utilization review (DUR),[15] which is a process by which a pharmacist analyzes a prescription to check for red flags signaling a potential diversion issue, and to ''assure that the prescription is for a legitimate medical purpose.'' Tr. 169; *see id.* at 189–90. Dr. Schossow defined a red flag as ''something on the prescription that alerts the pharmacist that the prescription may be being diverted or abused and that the pharmacist must do their due diligence to determine whether that red flag can be cleared or not.'' Tr. 189–90. When a pharmacist[16] is faced with a red flag, the red flag must be addressed and documented. Tr. 189–90, 198. Documented findings can be recorded on the prescription itself, within a patient profile, or in a note section of a pharmacy software program. Tr. 177. The witness opined that a lack of documentation indicates that the required analysis of a red flag was not performed by the dispensing pharmacist. Tr. 199–200. The witness conceded that she did not know whether any of the red flags she identified were actually analyzed and resolved by the Respondent,[17] but she made her opinion clear that a deficit in the adequacy of the documentation setting forth the pharmacist's DUR analysis brings a dispensing event below the Florida minimum standard of care, and that the DUR analysis can be set forth on the prescription itself or in a pharmacy's electronic records. Tr. 177, 740. According to Dr. Schossow, the mere existence of a red flag, in and of itself, does not always prohibit a pharmacist from filing a prescription;[18] it was her view that upon sufficient documented analysis, all red flags are potentially resolvable. Tr. 237. The Government's expert clarified early in her testimony that she was restricting her opinions to the minimum Florida standard of care, and not elucidating on best practices in the field of pharmacy. Tr. 175–76.

The Government's expert testified that she reviewed prescriptions and patient profiles corresponding to the Ten Patients[19] and determined that dispensing events depicted in those profiles and records presented numerous red flags, with no documented indications on the part of the Respondent of any attempts to resolve those red flags prior to filling the prescriptions in accordance with the standard of care for a Florida pharmacist. Tr. 431. One such red flag identified by the witness through the Respondent's paperwork was present in dispensing events where controlled substances were filled in high-risk combinations[20] that significantly elevate the risk for such things as central nervous system (CNS)/respiratory depression, overdose, coma, and death. Gov't Exs. 6, 7, 9–11, 13, 14, 22, 23, 25–27, 29; Tr. 215–16, 218–21; Stip. 33 (Patient JW); Tr. 268–69; Stip. 19 (Patient EA); Tr. 287–91, 294–95; Stip. 21 (Patient SD); Tr. 309–12; Stip. 25 (Patient DH);[21] Tr. 321–26; Stip. 27 (Patient DK);[22] Tr. 330–32; Stip. 29 (Patient JM);[23] Tr. 243–45; Stip. 35 (Patient CW). According to Dr. Schossow, under the Florida standard of care, filling these prescriptions would require documented *indicia* that the pharmacist reviewed the patient's history, reviewed the patient's information on the Electronic-Florida Online Reporting of Controlled Substance Evaluation database (E–FORCSE),[24] spoke with the doctor, spoke with the prescriber, inquired about the patient treatment plan, discussed function improvement of the patient, and discussed whether the patient had been apprised of the associated risks.[25] Tr. 204, 213–14, 216. The witness explained that there was no indication in the Respondent's records that the documentation requirement had been completed or addressed for the high-risk combination red flags that she identified. Gov't Exs. 6, 7, 9–11, 13–15, 22, 23, 25–27, 29, 32;[26] Tr. 240–41, 424–25 (Patient JW); Tr. 286, 371–75 (Patient EA); Tr. 295–300, 375–78 (Patient SD); Tr. 319, 321, 385–88, 397–98, 408–09 (Patient DH);[27] Tr. 329–30,

[14] Throughout her testimony, the witness would refer to various Florida statutes that, according to her, inform her opinion on the standard of care for a Florida pharmacist. In evaluating the role of an expert witness in the pharmacy context, the Agency has held that a pharmacy expert is ''not [expected to be] an expert in the details of state law, but she is required as a pharmacist to understand what conduct is outside of the usual course of professional practice in her state, whether that is derived from state law, mandatory training, standards of care or otherwise.'' *Suntree Pharmacy,* 85 FR 73,753, 73,772 (2020).

[15] During her testimony, the witness used the term ''DUR'' interchangeably to mean the process of a drug review, as well as for a finding made during the review that would warrant further review (*i.e.,* a red flag); this was confusing and unhelpful. *See, e.g.,* Tr. 187–88.

[16] It is Dr. Schossow's view that a diversion red flag may only be resolved by a pharmacist, never a pharmacy technician. Tr. 200.

[17] Tr. 446.

[18] Tr. 198.

[19] Patients JA, EA, SD, LH, DH, DK, JM, ST, JW, and CW.

[20] Dr. Schossow identified combinations of opioids and benzodiazepines that, when taken together, can potentially result in a dangerous suppression of the central nervous system. Tr. 204.

[21] Dr. Schossow testified that her opinion would not be altered by a brief temporal break such as two weeks between the in-conflict medications. Tr. 318.

[22] Dr. Schossow testified that her opinion was not altered by the fact that the prescriptions in conflict were not dispensed on the same day. Tr. 324.

[23] Dr. Schossow testified that her opinion was not altered by the fact that the prescriptions in conflict were dispensed several days apart. Tr. 338.

[24] E–FORCSE is the prescription drug monitoring program (PDMP or PMP) maintained by the State of Florida.

[25] The Government's expert also referenced guidelines (CDC Guidelines) issued on March 18, 2016 by the Centers for Disease Control and Prevention (CDC) regarding morphine equivalent dosages (MMEs). Tr. 205–06. The CDC Guidelines were the subject of official notice during the proceedings. ALJ Ex. 39. While the CDC Guidelines were the subject of some level of pre-hearing notice by the Government, ALJ Ex. 4 at 23, there was no specific notice that an MME at any particular level, standing on its own, constitutes a red flag requiring action by a pharmacy registrant. During her testimony, Dr. Schossow accepted the proposition that the CDC Guidelines were issued primarily to guide prescribers, not pharmacies. Tr. 503–04.

[26] During the hearing, Proposed Government Exhibit 16 was initially offered in the form of a compact disc and admitted with the condition that the Government provide a hard-copy version of the subset of pages that it seeks to rely upon. ALJ Ex. 44. After the hearing, the Government discovered that the relevant information within Proposed Government Exhibit 16 was also contained within Government Exhibit 32, and subsequently withdrew Proposed Government Exhibit 16. ALJ Ex. 47.

[27] Although the Respondent pharmacy's notes did reflect that its personnel conducted a conversation with the prescriber, the Government's expert held the view that the documentation was so lacking in detail that the applicable standard was not met. Tr. 387–95. Dr. Schossow was steadfast in her opinion that the level of documentation was wanting, but was unable or unwilling to specify any sort of a generic standard as to what the level of documentation needs to be to pass muster. *Id.*

409–13 (Patient DK); Tr. 346–47, 425–30 (Patient CW). Dr. Schossow's testimony regarding the absence of documentation also extended to Patient JM. Tr. 338–39, 413–16, 419–20; Gov't Exs. 11, 15, 27, 32. However, as highlighted in her testimony, the Respondent's records did contain notes documenting combination medication discussions between the pharmacy and Patient JM. Tr. 414–418, 471; Gov't Ex. 32 at 69. Specifically, the pharmacy notes include, *inter alia,* the following entries:

12/12/19 SPOKE TO MD OFFICE: PT HAS BIPOLAR SCHIZOPHRENIA/ANXIETY. MD IS AWARE OF COMBO DRUG (XANAX, TEMAZEPAM, HYDRO-MORPHONE, TIZANIDINE, MS CONTIN) NO SIGNS OF ABUSE. PT HAS BEEN ON MEDS SINCE 2010. PT HAS BUILT UP TOLERANCE.

12/16/19 SPOKE TO MD OFFICE: ABOUT COMBINATION OF OXYCO-DONE, MS CONTIN, XANAX, TIZANI-DINE, TEMAZEMAM. MD IS AWARE PT HAS BIPOLAR MORBIDITY. STATES MONITORS PT FOR ABUSE. NO SIGNS OF REPIRATORY DEPRESSION. PT HAS BEEN ON MEDS FOR OVER 5 YEARS.

Gov't Ex. 32 at 69. Similarly, a pharmacy note regarding Patient CW provides:

12/18/19 SPOKE TO MD ABOUT COMBINATION OF HYDROMORPHONE/ ALPRAZOLAM. PT HAS NO SIGNS OF SIQUALE. NO SIGNS OF ABUSE PT HAS BEEN ON MEDS FOR SEVERAL YRS. OK TO FILL. . . .

Id. at 13. To be sure, on their face, these highlighted pharmacy notes are temporally outside the Government's allegations related to Patients JM [28] and CW,[29] but they clearly do appear to contain analysis regarding the combination prescribing issue and coordination with the prescriber. These notes demonstrate that at some point the Respondent did commence documenting conversations with the prescribers on this issue, [which is a positive development that indicates an attempt by Respondent's pharmacists to fulfill their corresponding responsibility and operate within the usual course of professional practice. However,] inasmuch as the documented resolutions are dated after the charged misconduct, they supply no defense to the registrant in this case.

In reviewing the prescriptions that were filled by the Respondent, Dr. Schossow also identified anomalies in regard to dosages of controlled substance prescriptions that raised red flags. Specifically, the witness explained that certain prescriptions did not ''make pharmacological sense'' [30] because of the dosing combinations of long-acting and short-acting opioids.[31] Gov't Exs. 6–9, 11, 12; Tr. 274–76, 281–83; Stip. 19 (Patient EA); Tr. 296–97; Stip. 21 (Patient SD); Tr. 302–05; Stip. 23 (Patient LH); [32] Tr. 315–16; Stip. 25 (Patient DH); [33] Tr. 333–34; Stip. 29 (Patient JM); Tr. 339–41; Stip. 31 (Patient ST). And for at least one patient, Dr. Schossow testified that there were instances of therapeutic duplication, [34] which also presented a dosage-anomaly red flag. Gov't Ex. 11; Tr. 335–38; Stip. 29 (Patient JM). The witness testified that to address a dosage-anomaly red flag, a Florida pharmacist acting within the standard of care is required to speak with the physician to discuss the potential dangers and the patient's treatment plan, and then document the conversation.[35] Tr. 284–855, 318, 336–37. Through her testimony, the witness explained that she saw no indication in her review of the Government exhibits that the Respondent resolved, addressed, or documented the dosage-anomaly red flags. Gov't Exs. 6–9, 11, 12, 15, 22–25, 27, 28, 32; Tr. 286, 371–75 (Patient EA); Tr. 298–300, 375–78 (Patient SD); Tr. 308, 378–80, 384 (Patient LH); Tr. 319, 321, 385–88, 397–98, 408–09 (Patient DH); Tr. 338–39, 413–16, 419–20 (Patient JM); Tr. 342–43, 420–23 (Patient ST).

Dr. Schossow also testified that instances where customer-patients of the Respondent drove long distances to obtain and/or fill controlled substance prescriptions were red flags that must be addressed and resolved. Tr. 232–34; Gov't Exs. 5, 8, 10, 12, 13, 21, 24, 26, 28; Tr. 232–36 (Patient JW); Tr. 248–50 (Patient JA); Tr. 305–06 (Patient LH); Tr. 326–28 (Patient DK); Tr. 341–42 (Patient ST); ALJ Ex. 19, Attachs. A, C. [Dr. Schossow testified that] a patient driving long distances to fill a controlled substance prescription presents a red flag because of concerns ''for the safety of the patient'' as they could potentially be driving under the influence of controlled substances. Tr. 232–34. In order to address this long-distance red flag, a Florida pharmacist acting within the standard of care, at least according to Dr. Schossow, would need to question the patient on whether they were personally driving, question the prescriber on whether they ''discussed the dangers of the dosing of the medication in regards to operating a motor vehicle,'' [36] and then document the conversation/resolution.[37] Tr. 238–39; *see also id.* at 306–07, 328. [Omitted as superfluous. As discussed in more detail below, the Chief ALJ found that Dr. Schossow's testimony regarding the distance red flag was not convincing. I agree, and I do not give any weight to this testimony in my Decision. I have omitted portions of the RD's discussion of this red flag for brevity.]

Cash payments for controlled substances were also identified by Dr. Schossow as a red flag of potential diversion. Tr. 222–23, 457; Gov't Exs. 5–14, 21–29; Tr. 229–30; Stip. 34 (Patient JW); Tr. 242, 244; Stip. 18 (Patient JA); Tr. 269–70; Stip. 20 (Patient EA); Tr. 296–97; Stip. 22 (Patient SD); Tr. 305; Stip. 24 (Patient LH); Tr. 313; Stip. 26 (Patient DH); Tr. 326; Stip. 28 (Patient DK); Tr. 332–33; Stip. 30 (Patient JM); Tr. 341; Stip. 32 (Patient ST); Tr. 346; Stip. 36 (Patient CW). Dr. Schossow explained that an indication on a

[28] OSC/ISO Allegation 7.e charges that combination prescriptions between January 9, 2019 and August 23, 2019 were dispensed by the Respondent to Patient JM without documented evidence that the identified combination red flag was resolved. ALJ Ex. 1 ¶ 7.e.

[29] OSC/ISO Allegation 7.g charges that combination prescriptions between February 19, 2019 and August 28, 2019 were dispensed by the Respondent to Patient CW without documented evidence that the identified combination red flag was resolved. ALJ Ex. 1 ¶ 7.g.

[30] Tr. 281.

[31] Certain controlled substances are prescribed to be taken scheduled, in order to maintain the medication at a certain level in the body consistently. Tr. 275–76. While other controlled substances are prescribed to address breakthrough pain, or episodic pain, on an as-needed basis. Tr. 276–77. Here, Dr. Schossow testified that the Respondent was filling prescriptions where controlled substances that are usually prescribed for breakthrough pain were prescribed on a scheduled basis. Tr. 274–75.

[32] The witness was unmoved by the fact that the prescription sig was marked ''PRN,'' signifying that the medication was to be taken on an ''as needed'' basis. Tr. 302–03.

[33] Regarding Patient DH, Dr. Schossow's opinion is that to resolve an identified dosing red flag within the standard of care, a Florida pharmacy registrant would be required to demonstrate documented ''careful justification of why [the patient] would need so much [medicine] or the attempt of trying to lower it to a safer dose with the physician.'' Tr. 409. [The Chief ALJ determined that the standard outlined by Dr. Schossow was too onerous to impose on pharmacists. However,] there is a sufficient lack of documentation in this case that it is not necessary to reach the issue of whether Dr. Schossow's elevated standard of documentation delivered here meets or exceeds the required threshold. [Respondent's failure to document any resolution of this red flag was outside the usual course of professional practice, and a violation of its corresponding responsibility.]

[34] The witness defined therapeutic duplication as when two controlled substances that act pharmacologically the same are prescribed together. Tr. 335–36.

[35] [Omitted for clarity].

[36] Tr. 307.

[37] In one particular note for Patient LH, the Respondent wrote that the patient lived in Naples, Florida. Tr. 380; Gov't Ex. 32 at 80. The witness testified that this type of notation is insufficient and that the standard of care requires communication and documentation regarding whether the patient is actually driving. Tr. 380.

particular prescription of ''cash'' means that the price of the prescription was not ''charged to an insurance company, or worker's comp.'' [38] Tr. 222–23. The Government's expert explained that, in her opinion, if a patient did pay in ''cash'' that she would assume the patient had insurance but was choosing not to utilize their insurance; a scheme she explained, in her experience, is practiced by drug diverters.[39] Tr. 223–28. Dr. Schossow admitted that she could not know for certain whether a patient had insurance or not simply by seeing the notation ''cash'' on a prescription. Tr. 226. The witness also acknowledged that where a pharmacy is out of network, the customer patient can submit the insurance reimbursement claim to the insurer. Tr. 537. According to Dr. Schossow, in order to resolve a cash red flag, within the standard of care, a Florida pharmacist is required to ask the prescribing physician whether the patient has insurance and document the finding.[40] Tr. 228–29, 239, 306. A notation by the pharmacy staff that a customer-patient did not have insurance coverage [41] was, in Dr. Schossow's view, insufficient to resolve the red flag of cash payment. Tr. 367, 374, 428. Even a case where the registrant pharmacy documented that it was not contracted with the customer-patient's insurance carrier was insufficient to satisfy the standard outlined by Dr. Schossow based on her expressed innate suspicion of a customer who would not, on that occasion, seek out a different pharmacy that accepted the prescription coverage benefit.[42] Tr. 411. [Omitted for brevity. The Chief ALJ found that Dr. Shossow's testimony about this red flag was not convincing and that her standard for resolving this red flag was too burdensome and illogical to set the minimum standard of care in Florida. The Chief ALJ did not sustain the Government's allegations regarding this red flag, and the Government took Exception to this finding. As discussed below, I find that it is unnecessary for me to reach this issue because there is substantial other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest. [43] [44] [45] [46] [47] [48] [49] [50]

Overall, Dr. Schossow's testimony, although not without its warts, was generally authoritative and amply supported by the admitted evidence of record. While her overall presentation was generally objective, her [testimony that she] ''had a lot of patients in the community arrested for opioid and other controlled substance fraud and abuse,'' [51] and her underlying assumption that customer-patients should be assumed to be abusers [52] (although she had no information that this may have been the case regarding any of the Ten Patients), [53] were certainly concerning aspects of her testimony. [It was also concerning that Dr. Schossow testified that] she had been a member of the Florida Board of Pharmacy and then denied that this was ever the case. [Omitted for brevity. I agree with the Chief ALJ that this testimony was confusing, but there is insufficient evidence on the record about how the Board operates and what role Dr. Schossow was referring to that would permit me to ascribe any level of intent to Dr. Schossow regarding this statement. Based on my review of the record, I did not discern any intent to mislead the Tribunal, but certainly at least her initial statement gave an incorrect impression and I consider this statement in the same manner as the Chief ALJ did below.]

Dr. Schossow's testimony also contained isolated occasions where she arguably presented as confusing,[54] defensive, even bordering on evasive, [55] and the ''on-the-Board''/''not-on-the-Board'' feature was [confusing], but she has no objective stake in the outcome of the proceedings, and there is nothing present in the record or her testimony that would mortally undermine her credibility and reliability. On those points where her testimony was found reliable and persuasive in this RD, the witness provided sufficient, detailed, cogent support for her views. Of the two experts who testified in these proceedings, her shortcomings notwithstanding, she is the more reliable and persuasive, and where her testimony was at variance with the Respondent's expert, it is Dr. Schossow's opinion which will be relied upon.

The Respondent's Case [*D]

The Respondent's case consisted of testimony from the Respondent's owner and an expert witness.

Dr. Daniel E. Buffington, Pharm.D.

The Respondent presented the testimony of Dr. Daniel Buffington, Pharm.D. Dr. Buffington's CV [56] reflects that he earned his Doctorate in Pharmacy in 1987, completed a pharmacy residency in 1988, and concluded a pharmacy fellowship in 1989 that focused on pharmacy practice and clinical pharmacology. Tr. 792–94; Resp't Ex. 12. The witness testified that he has held a faculty position at the University of South Florida, Colleges of Medicine and Pharmacy since the early 1990s, along with various other academic appointments and positions where he has taught a myriad of topics regarding pharmacotherapy and clinical pharmacology. Tr. 792, 794–95. Dr. Buffington explained that, although he is not licensed as a consultant

[38] During the course of his testimony on the issue, the Respondent's owner testified that ''cash'' can mean currency, a credit card, or a check. Tr. 635.

[39] The Government presented no evidence that any of the Ten Patients were or are drug diverters. This assumption played no role in the Government's noticed theory of its case. ALJ Ex. 1.

[40] According to Dr. Schossow, a notation that simply states that the patient does not have insurance is insufficient to meet the standard of care in Florida. Tr. 374. Dr. Schossow explained that even where a prescription contains such a notation, it is incumbent upon the pharmacist to contact the prescriber to ensure a true lack of insurance, Tr. 374, but conceded that ''many'' of the prescriptions she reviewed in this case did have an indication from the prescriber that the customer-patient was uninsured, Tr. 471. Thus, by Dr. Schossow's view, even where the pharmacy has apparently determined that the customer-patient is without prescription insurance coverage and documented that conclusion on the relevant scrip, the additional step of contacting the *prescriber* and documenting the results of that conversation are required to meet the minimum standard of care in Florida. As discussed, *infra,* this makes no sense.

[41] *See, e.g.,* Gov't Ex. 32 at 13 (pharmacy note entered outside the charged conduct period reflecting the Respondent's conclusion that Patient CW paid cash because she did not have insurance).

[42] [Footnote omitted where text was deleted.]

[43] [Footnote omitted where text was deleted.]

[44] [Footnote omitted where text was deleted.]

[45] [Footnote omitted where text was deleted.]

[46] [Footnote omitted where text was deleted.]

[47] [Footnote omitted where text was deleted.]

[48] [Footnote omitted where text was deleted.]

[49] [Footnote omitted where text was deleted.]

[50] [Footnote omitted where text was deleted.]

[51] Tr. 137.

[52] Tr. 368.

[53] Tr. 444–45.

[54] *See, e.g.,* Tr. 399–408. The witness volunteered that the pharmacy notes she was reviewing on the stand were not the same as the notes she reviewed prior to her testimony. *Id.* This anomaly was never cogently explained by the witness. [Omitted for brevity. I agree with the Chief ALJ that there was no ''cognizable prejudice to the interests of justice or the Respondent's case'' from Dr. Schossow's confusion about which notes she reviewed before the hearing, because Dr. Schossow was clear during her testimony about what materials she reviewed and how she formed her opinions.]

[55] *See, e.g.,* Tr. 243–44 (multiple attempts taken to get the witness to state that the paperwork she examined did not have any indication as to whether the customer-patients had insurance with prescription drug coverage); Tr. 291–93 (significant equivocation on whether identified red flags are resolvable, and if yes, how so); Tr. 448–49 (significant equivocation on answering whether, during her analysis, she had identified violations beyond failure to document red flag resolutions); Tr. 451–52 (significant equivocation in addressing the straightforward question of whether she had ever read the footnotes, any of the footnotes, in a specified guidance document issued by the CDC).

[*D] Throughout the Respondent's case, I have made some minor adjustments to the wording where noted for brevity and for clarity and to reflect more of my style. *See supra* n. *C.

[56] Resp't Ex. 12.

pharmacist in Florida,[57] his pharmacy background has included some consultation, clinical research, and pharmacy work as both a clinical and retail pharmacist. Tr. 796–97. His current business, Clinical Pharmacology Services ''is a licensed pharmacy [that] also provides direct patient consultation, manages clinical research trials, and provides drug information support for health systems, medical practices, but also forensics for law enforcement, government agencies.''[58] Tr. 796. The witness testified that he has also served as an expert in numerous state and federal cases and has participated on panels relative to Florida legislative initiatives regarding administrative code provisions. Tr. 814–15. Dr. Buffington was tendered[59] and, without objection from the Government, accepted[60] as an expert witness in Florida pharmacy practice under Florida and federal standards, and the standard of care for pharmacists practicing in the state of Florida.[61] Tr. 813.

According to Dr. Buffington, under the applicable standard of care for dispensing controlled substances in Florida, a pharmacist is expected to assess every new and refill prescription presented to them by a patient.[62] Tr. 823. Dr. Buffington summarized his view of applicable statutes governing the standard in Florida as follows:

> [T]he pharmacist as the specialist in this area of pharmacology and drug-related issues is expected, per Florida Board of Pharmacy and regulations, to do [sic] on each new and refill prescription, to evaluate, prior to dispensing, seven key criterions that look at common drug-related problems. Some of those may be drug interactions or duplications in therapy, dosing, drug allegories, wide variety.

Tr. 823. Regarding the issue of documentation, the witness holds the view that there is essentially no requirement that a pharmacist document any analysis employed for resolving any red flag issue that arises relative to potential controlled substance diversion so long as the medication is ultimately dispensed. According to Dr. Buffington, the Florida state standard of care is also apparently dependent upon whichever commercial software system any pharmacy elects to purchase and utilize. The colloquy between the Respondent's counsel and its expert is [notable]:

> Q. Does the standard of care in Florida require that a pharmacist document, at all, resolution of any issues by the prospective drug utilization review?
>
> A. No, sir. It's the pharmacist's individual prerogative and up to their system. In some cases, their pharmacy software system may afford some of that by process. Others, there's data entry fields. It doesn't have to be solely contained in the pharmacy software. It can be in secondary software. It can be hand-written. It can be maintained in a variety of ways. They leave that up to the personal judgment and prerogative and systems at each pharmacy.

Tr. 823–24. When asked to clarify if the standard really depends on something as subjective and unregulated as what commercial software is employed by individual pharmacies, the [Respondent's expert testified]:

> No, sir. I'm saying it's up to the pharmacist as to which method, or collective methods, they wish to document. There is no format. There is no content-specific requirements with which a pharmacist has to document the addressing of those issues.

Tr. 824. By this view, a pharmacy that elects to purchase a substandard software system apparently can generate a lower standard of care than a pharmacy that acquires a more vigilant system. By this same reasoning, a pharmacy could even potentially escape regulatory scrutiny by the acquisition of a subpar software system. Suffice it to say that the notion that state and federal regulators intended to design a system that creates a perverse incentive to deploy bad software to dodge responsibility is unpersuasive. When asked again for clarification, the Respondent's expert, after some [discussion] about whether DURs and red flags[63] are homonyms, stated his opinion:

> [T]here is no requirement for the documentation of red flags, or DURs, in the State of Florida. There is opportunity to document. There is a requirement, or a duty, to address those items. The—the—the DURs. There is no Florida-based, or DEA-based recognition for documenting red flags.

Tr. 825.

The Respondent's expert later clarified that while processing a DUR, that even when a pharmacist encounters a potential red flag issue through its software, if ''it didn't need resolved, there's no need to record it.'' Tr. 913. Documentation, according to Dr. Buffington, is only required ''[i]f there's something to resolve.'' Tr. 914. When asked if a heightened level of suspicion that supported a decision to decline to dispense would ever merit some level of documentation, Dr. Buffington [testified]: ''Well, first of all, I'm going to work through whatever that question or suspicion is, and *it's not going to be documented—or, it's not going to be dispensed*.'' Tr. 917 (emphasis supplied). Following this approach, a pharmacist can subjectively determine that there is no issue to be resolved, document nothing, and be within the Florida standard of care. And since nothing is documented, the only correct assumption available to regulators, according to the Respondent's expert's view, is that everything was correctly assessed and resolved. [Omitted.] Thus, according to Dr. Buffington, there is no requirement under the applicable standard of care to document any resolution regarding any indication of diversion on the part of any patient or prescriber, no matter how egregious or how potentially dangerous, so long as the decision was ultimately made to dispense.

Dr. Buffington [also testified that the phrase] ''if it wasn't documented, it wasn't done'' has no application to a pharmacy's obligation to document the resolution of red flags because there is no obligation to document the resolution of red flags.[64] Tr. 825–26. [Dr.

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[57] Tr. 793.

[58] Dr. Buffington explained that his work includes consulting with retail pharmacies regarding their compliance with relevant Florida law provisions. Tr. 816.

[59] Tr. 799–800.

[60] During *voir dire,* the witness was combative and evasive even in answering straightforward questions regarding his qualifications. *See, e.g.,* Tr. 805–09.

[61] Tr. 799.

[62] The witness testified that in preparation for his testimony he reviewed relevant Florida administrative code sections. Tr. 815. In evaluating the role of an expert witness in the pharmacy context, the Agency has held that a pharmacy expert is ''not [expected to be] an expert in the details of state law, but [ ]he is required as a pharmacist to understand what conduct is outside of the usual course of professional practice in [his] state, whether that is derived from state law, mandatory training, standards of care or otherwise.'' *Suntree Pharmacy,* 85 FR 73,772.

[63] In fact, the Respondent's expert communicated a certain hostility to even the concept of red flags, pointing out during his testimony that red flags is ''a colloquial term,'' Tr. 832, and in the guidance issued by Florida and DEA ''there are no definitions of red flags, nor is there any published requirement that guides pharmacy practice on what, and how, to document those,'' Tr. 825. At another point in his testimony, the witness stated he would not document the resolution of a controlled substance red flag because he ''can't find a consistent definition of that colloquial term.'' Tr. 936–37. This proposition [is inconsistent with] many years of Agency adjudication addressing red flags of potential diversion [supported by credible expert testimony] and longstanding acceptance of the term. *See, e.g., Suntree Pharmacy,* 85 FR 73,769 (''When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription.'') (collecting cases); *Morning Star Pharmacy & Medical Supply 1,* 85 FR 51,045, 51,060 (2020) (same).

[64] The witness was unpersuaded by the argument that without adequate documentation another pharmacist encountering the same customer-patient would be without knowledge of a red flag determination made by a predecessor pharmacist or be able to pass down information to a successor pharmacist. Tr. 960–61.

Buffington testified that pharmacists are not obligated] to document the resolution of any controlled substance red flag because he ''can't find a consistent definition of that colloquial term.'' Tr. 936–37; *see also id.* at 940, 945. The witness suggested that requiring a level of documentation beyond this minimalist view would require the use of ''court reporters in the pharmacy.'' Tr. 939. [Omitted for brevity.] For, as Dr. Buffington reasoned, it is the pharmacist alone who exercises ''professional prerogative,'' and as he, himself put it, ''someone else not understanding the core facts of [his] job doesn't make what [he's] doing incorrect.'' Tr. 915–16

Dr. Buffington [offered an interpretation of Florida law that was not persuasive. Tr. 826–27, 924 (discussing subsection (3)(a) of rule 64B16–27.831 of the Florida Administrative Code (Florida Pharmacy Standards Statute or FPSS).] Subsection (3)(a) of the FPSS lists steps to be taken by a pharmacist before *declining* to dispense a controlled medication. Fla. Admin. Code Ann. r. 64B16–27.831(3)(a). The FPSS requires a pharmacist to reach out to the patient and prescriber, or check E–FORCSE in place of either (but not both) of those contacts prior to *declining* to dispense a controlled substance. *Id.* r. 64B16–27.831(3)(a), (b). [Although Dr. Buffington agrees that a pharmacist must document his decision to *decline* to fill a prescription, *see* Tr. 827, he does not believe that a Florida pharmacist has a] duty to evaluate the validity of the prescription or to document his/her analysis or findings [if the pharmacist ultimately fills the prescription.] There is no exposure so long as he/she dispenses the drugs. [This testimony is inconsistent with the] FPSS and other provisions of Florida law. The FPSS specifically instructs:

> There are *circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance;* however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

Id. r. 64B16–27.831(2) (emphasis supplied). It is clear that in its description of ''circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance,'' the Florida legislature was referring to what has been ubiquitously referred to by DEA, the regulated community, and the industry, as a red flag of potential diversion. Upon encountering one of these, the FPSS directs pharmacy practitioners to consult with the prescribers, patients, and/or E–FORCSE. The opening section of the FPSS instructs that ''[p]harmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the [controlled substance] prescription.'' *Id.* r. 64B16–27.831. Thus, upon encountering a ''circumstance that may cause a pharmacist to question the validity of a prescription for a controlled substance'' [65] (*i.e.,* a red flag of potential diversion), a pharmacist must reach out to either the prescriber or the patient, and where appropriate, in place of one of those two sources (but not both) the pharmacist may resolve a red flag by utilizing E–FORCSE. *Id.* The Florida legislature has also directed that ''[t]he pharmacist shall record any related information indicated by a licensed health care practitioner.'' Fla. Admin. Code Ann. r. 64B16–27.800(2) (Florida Pharmacy Patient Record Statute or FPPRS). The FPPRS also directs pharmacists to create a record of ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* r. 64B16–27.800(1)(f). Hence, contrary to Dr. Buffington's view, under Florida law and the applicable standard of care, a pharmacist who encounters a red flag is required, before resolving the red flag [and filling the prescription], to contact the prescriber and/or patient and is required to document both of those interactions.[66] [*E]

Contrary to Dr. Buffington's testimony that [it should be assumed that a pharmacist has resolved any potential red flags if he decides to fill the prescription], the Agency has made it clear that it is unwilling to credit ''[*p*]*ost hoc* written or oral justifications'' for actions taken as a registrant that were not documented, *George Pursley, M.D.,* 85 FR 80,162, 80,171 n.28 (2020); *see Lesly Pompy, M.D.,* 84 FR 57,749, 57,760 (2019). In fact, the Agency has accepted the premise that ''it would be reasonable to draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the failure to document the resolution in any manner . . . .'' *Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31,310, 31,335 (2016). [Omitted for brevity].

Dr. Buffington also testified that filling combination prescriptions of higher dosages of short-acting medications and lower dosages of long-acting medications does not fall below the standard of care.[67] Tr. 877. Likewise, the witness rejected medication combinations referred to as ''cocktails'' as a red flag, stating that ''[e]very patient who has multiple drugs in their regiment is a cocktail [sic].'' Tr. 955. The witness opined that simultaneously dispensing such combinations (either opioids and benzodiazepines, or opioids, benzodiazepines, and muscle relaxers) ''[a]bsolutely [does] not'' fall below the applicable standard of care for Florida pharmacists. Tr. 863–64. Dr. Buffington explained that the presentation of such controlled substance combinations is ''not a potential issue, the fact that it may have been flagged in a DUR, unless the patient is experiencing complications.'' Tr. 865. This view is not only inconsistent with the opinion of Dr. Schossow, but also the view of the Agency, which has sustained cocktail combinations as red flags of potential diversion requiring documented resolution. *See, e.g., Suntree Pharmacy,* 85 FR 73,756 (acknowledging that DEA ''has long discussed cocktails'' as a red

[65] *Id.* r. 64B16–27.831(2).

[66] Dr. Buffington's opinion that there is no requirement for a Florida pharmacist to consult with prescribers regarding the existence of a clinical plan, tapering, or titration (Tr. 828) [is also not credible].

[*E] The Chief ALJ's interpretation that Florida law requires pharmacists to document the resolution of red flags is supported by a plain language reading of the various provisions of the Florida Administrative Code and by credible expert testimony about the importance of documentation in Florida. I agree with the Chief ALJ's interpretation, and I agree with his conclusion that Respondent violated Florida law by failing to document the resolution of red flags. However, my Decision does not rely on any interpretation of Florida law, because, in failing to document the resolution of red flags, Respondent violated federal law in addition to state law. Dr. Schossow offered credible expert testimony that failing to document red flag resolution is outside the usual course of professional practice in Florida. Although Dr. Buffington offered conflicting testimony that documentation is not required in the usual course of professional practice, I agree with the Chief ALJ that Dr. Schossow's testimony regarding documentation requirements was considerably more credible. Thus, as discussed in more detail *infra,* I find that Respondent repeatedly violated federal law by filling numerous prescriptions outside the usual course of professional practice without adequately addressing, resolving, or documenting red flags in violation of its corresponding responsibility. *See* 21 CFR 1306.04(a) and 1306.06. Respondent's violations of federal law serve as an independent basis for my conclusion that Respondent's registration is inconsistent with the public interest and that revocation is the appropriate remedy in this case.

[67] The witness reasoned that such occurrences can happen because ''[y]ou build a therapeutic regimen that meets that patient's specific needs and lifestyle.'' Tr. 876. ''[Y]ou don't see that and assume that it's somehow indicative of inappropriate patient care.'' Tr. 878.

flag issue). Furthermore, Dr. Schossow's view of the appropriate uses of immediate-release and extended-release medications is more persuasive than Dr. Buffington's summary dismissal of the issue.

The witness was likewise dismissive in considering the applicability of the CDC Guidelines issued in 2016 regarding controlled substance dispensing. Dr. Buffington testified that the CDC Guidelines had no impact on the standard of care for pharmacists practicing in Florida. Tr. 819, 907–08. According to the Respondent's expert, the CDC Guidelines amount only to a ''recommendation to help educate physicians,'' and a mere ''guideline, or recommendation.'' Tr. 820; *see also id.* at 903 (''Typically all guidelines are recommendations, or instructional for—they're not thresholds or limitations on practitioners.'').

[However,] the CDC Guidelines reveal considerable specificity in their guidance to prescribers (and by extension, to pharmacists [filling prescriber's prescriptions]), including advisals to commence opioids at the ''lowest effective dosage,'' preferences for immediate-release over extended-release opioids at the commencement of opioids as a pain treatment modality, specific guidance regarding MME levels exceeding 50, and a preference for ''[n]onpharmacologic therapy and nonopioid pharmacologic therapy'' for chronic pain. ALJ Ex. 39, Attach. A at 16. Although the issue in this case is whether a particular prescription raises a red flag of potential diversion, Dr. Buffington altered the subject into whether the CDC Guidelines imposed a ''hard stop, hard block, or change'' on prescribers,[68] which [is not relevant to the Government's allegations. Although Dr. Buffington is correct that the CDC Guidelines do not impose a ''hard stop,'' the Guidelines issue clear guidance to medical professionals about prescribing high dosages of opioids:]

> Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.

ALJ Ex. 39, Attach. A at 16. At another point in his testimony, Dr. Buffington allowed that the CDC Guidelines advise practitioners to ''use caution if [they]'re getting to 90 [MME], or be very clear that [they] understand and have a rationale for doing that.'' Tr. 908. Whatever be the limits of the finer points of the CDC's guidance, to dismiss an encountered titration that exceeds 90 MME/day as an insignificant non-issue to pharmacy practice is not a fair inference that can or should be drawn by the plain language of the CDC Guidelines. Neither is the subsequent policy clarification[69] (CDC Clarification) issued by the CDC particularly supportive of Dr. Buffington's premise that it was issued to address ''key areas where the [CDC] realized people, or courts, may be misrepresenting the [CDC G]uidelines as a fixed or regulatory threshold.'' Tr. 830–31. The principal focus of the CDC Clarification was focused on ensuring that practitioners did not read the CDC Guidelines as supporting dangerous, sudden, and drastic discontinuations of opioid therapy to the detriment of patients. ALJ Ex. 39, Attach. B at 1–2. There is nothing in the plain language of the document that runs counter to identifying a red flag of potential diversion under the appropriate circumstances based in some part on high opioid dosages.

The witness was similarly dismissive in addressing a warning[70] issued by the U.S. Food and Drug Administration (FDA) concerning the extreme dangers posed by combining opioids and benzodiazepines (the Black Box Warning). ALJ Ex. 39, Attach. C. The Respondent's expert acknowledged that a black box warning connotes a ''heightened level of warning,'' that should inform a pharmacist's decision making, but insisted (despite the FDA's decision to issue the warning) that it contained no new information and was merely an advisal to prescribers that these ''very low incident'' complications could occur. Tr. 909. Although in its drug safety communication setting for the Black Box Warning, the FDA refers to black box warnings as its ''strongest warnings,''[71] the Respondent's expert [did not consider the warning to be notable, and further testified that ''the combined use of the two [medications] presents no complication or problem for healthcare professionals specifically in chronic pain . . . .'']. Tr. 909, 959. This view arguably stands in some tension with the plain language contained in the Black Box Warning:

> *Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate.* If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. *Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants,* including alcohol.

ALJ Ex. 39, Attach. C at 1 (emphasis supplied). Although Dr. Buffington reads the Black Box Warning as an authorization to continue to use (not limit) this combination,[72] the FDA apparently holds the view that health care officials should limit the combined prescribing of opioids and benzodiazepines to situations where other treatment options are inadequate. *Id.* Notwithstanding this limitation (couched in directive, not passive language), Dr. Buffington's position is apparently that the ''avoid'' aspect of the warning should be deemphasized over a recognition that the two medications can be prescribed together. In any event, the Government never argued that the combination is *per se* prohibited, but rather that the combination raises a dispensing red flag that requires documented resolution to meet the standard of care. [Relocated]

In specifically addressing cash red flags, the Respondent's expert opined that ''the method of payment is somewhat irrelevant'' and that the standard of care ''[a]bsolutely [does] not'' require pharmacists to investigate the rationale for a customer-patient utilizing cash payments or insurance. Tr. 833–34; *see also id.* at 953. Dr. Buffington reasoned that pharmacists ''have that capacity to understand that patients' payment methods often ebb and flow based on [insurance] coverage. . . . There are just so many variables that there is no predictive validity, or use, of presuming cash payment to be a problem.''[73] Tr. 833. Regarding the position of the Government's expert that a pharmacy is required to contact a prescriber to confirm prescription coverage details, Dr. Buffington persuasively testified that a ''medical benefit does not always coincide with a drug-spend benefit.'' Tr. 834. While this perspective is reasonable, declaring cash as *never* a relevant consideration [is not balanced and not credible]. The view of the Respondent's expert that cash is always patently irrelevant to the evaluation of dispensing events is in considerable

[68] Tr. 830, 862–64.

[69] ALJ Ex. 39, Attach. B.

[70] Also known as a boxed warning.

[71] ALJ Ex. 39, Attach. C at 1.

[72] Tr. 909.

[73] Dr. Buffington reasonably opined that requiring a pharmacy registrant to reach out to a physician's office to investigate a patient's insurance coverage is idiosyncratic because the insurance coverages are different. Tr. 834.

tension with the Agency's view based on credible expert testimony. *See, e.g., Suntree Pharmacy,* 85 FR 73,757 n.13 (sustaining ALJ's finding based on credible expert testimony ''that cash is a red flag in combination with other red flags''); *Pharmacy Doctors Enters.,* 83 FR 10,876, 10,891 (2018) (same). As can fairly be stated about other aspects of Dr. Buffington's presentation, he was inconsistent regarding this issue. At another point in his testimony the witness seemed to nominally retreat from this absolutist opinion and suggested that cash could indeed potentially be a red flag. Tr. 955. This was confusing. As discussed elsewhere in this recommended decision, although the rationale of the Government's case for cash as a red flag in the present case (*to wit,* the pharmacy must call the doctor regarding pharmacy insurance coverage) was unpersuasive, [I also decline to credit Dr. Buffington's testimony that cash payments are never a red flag.[74] *See infra* for further discussion of cash payments. Omitted for brevity].

The Respondent's expert similarly dismissed any considerations of long travel distances as a potential red flag. When asked whether distance could be a potential red flag, his response was ''[a]bsolutely not.'' Tr. 948. Beyond his eminently valid point that a pharmacist possesses no capacity to limit the driving habits of its customer-patients beyond recommendations,[75] Dr. Buffington was unequivocal in his rejection of the whole concept, declaring:

> There's no logical rationale, or supportable—and certainly no regulatory—oversight over that. You could live in the [Florida] Keys and fill in the [Florida] Panhandle. You could fill at a pharmacy you prefer, or have worked with, where you lived previously. One that's—there are just so many variables, from your home, your office, your doctor's office—it's purely your choice as a consumer. There's no predictive validity that where—in fact, you can fill out-of-state. There's not a problem for your prescription. So, there is just no utility in attempting to use that as a metric.

Tr. 834–35. The witness opined that ''distance is of no predictive value in and of itself . . . .'' Tr. 949. [He testified that he was not obligated] to document a distance red flag, adding ''I have no obligation to take someone else's variable and write something down.''[76] Tr. 951. Certainly, Dr. Buffington's broad denunciation of distance as a red flag is directly contrary to [prior Agency decisions based on credible expert testimony]. *See, e.g., Heavenly Care Pharmacy,* 85 FR 53,402, 53,417 (2020) (recognizing based on credible expert testimony long distance as a valid red flag); *Pharmacy Doctors Enters.,* 83 FR 10,885 (same); *Hills Pharmacy, LLC,* 81 FR 49,816, 49,839 (2016); *Holiday CVS, L.L.C.,* 77 FR 62,316, 62,321–22 (2012) (same); *E. Main St. Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (same). [Omitted for brevity.] As was not uncommon throughout the course of his presentation, Dr. Buffington produced an answer favorable to the Respondent by changing the question. When *asked* if distance could support a diversion red flag (*i.e.,* an issue to be resolved prior to dispensing), the witness *answered* the question of whether such an issue was potentially *resolvable,* which was a premise that comprised no part of the Government's case. [Omitted for brevity.] Although the rationale employed by the Government's expert (motor safety) was unpersuasive in this case, the categorical dismissal of distance as a red flag under all circumstances detracted from the reliability that should be afforded to Dr. Buffington's testimony.

The witness similarly transposed the issue of illogical medication dosing combinations as a red flag. When queried on the subject, Dr. Buffington [changed] the issue into whether such dosing variations between extended-release and short-acting medications were inappropriate under *all* circumstances, which was [not the Government's or Dr. Schossow's theory]. Tr. 877–81. The issue in the case is whether the Respondent pharmacy was presented with a red flag that required follow-up, resolution, and documentation. Like most red flags, the question presented may be (and often is) subject to resolution. Dr. Buffington's view on the issue of illogical medication dosing is divergent from that of Dr. Schossow, but the Government expert's testimony on this issue was better explained, more persuasive, less evasive, and more reliable.

[The Chief ALJ questioned the credibility of Dr. Buffington's testimony that he performs physical examinations on pharmacy customers. Tr. 920–21. I agree that this testimony was unusual, but I have omitted the discussion as it does not ultimately impact my Decision.]

The Respondent's expert testified that he reviewed the relevant documents[77] for the Ten Patients from the Respondent pharmacy and testified that the Respondent's controlled substance dispensing did, in his opinion, meet the standard of care in Florida for each of the prescriptions at issue in this matter. Tr. 845, 850–51, 859, 881. Dr. Buffington testified that he saw no deviation from the standard of care on the part of the Respondent in terms of over-utilization and under-utilization,[78] therapeutic duplication,[79] drug-disease interactions, drug-drug interactions,[80] drug dosages or treatment,[81] drug-allergy interactions, and clinical abuse and misuse.[82] Tr. 845, 854, 863, 865, 868–69.[83] Although it was never

[74] [Omitted.]

[75] Tr. 873.

[76] After repeatedly [testifying that distance was not] a potential red flag issue, the witness testified that he ''already said it could'' be a red flag. Tr. 952. At another point in his testimony, the witness, in response to a direct query of whether distance could ever be a red flag, [testified]: ''It could, but I've already stated we already have methods for dealing with that, and I wouldn't call it a red flag.'' *Id.* at 954. [Omitted for brevity.] The inconsistencies further denigrated any ability to credit Dr. Buffington's opinions.

[77] Dr. Buffington testified that, in addition to the Government Exhibits, he also reviewed Proposed Respondent Exhibits that were not offered or admitted during the course of the hearing. Tr. 845, 880.

[78] The witness testified that this is ''a patient-specific issue.'' Tr. 852. This is another instance where the witness replaced the issue posed with one that [he preferred to discuss]. When asked about under-utilization, something that could potentially be a red flag of abuse requiring resolution, the witness substituted his analysis that the CDC Guidelines placed no hard cap on MME levels, Tr. 853–57, which was not among the Government's theories. The issue in the case was never whether a prescriber can elect to use his/her professional judgment, but whether a particular dosage strength can raise a potential red flag requiring inquiry, resolution, and documentation. The witness's responses on this issue were also (as many other answers were) seemingly dependent upon the limits of the commercial software purchased by an individual pharmacy, which, as discussed in detail, *supra,* cannot serve as a reasonable, objective yardstick for whether a DEA pharmacy registrant has met the applicable standard of care.

[79] The witness defined therapeutic duplication as when two medications of the same class, or two medications with the same pharmacologic effect, are prescribed together. Tr. 854–55.

[80] Dr. Buffington explained that when a pharmacist encounters a drug-drug interaction, they are ''looking for predominantly metabolism, secondarily effects as to whether or not that potential for conflict is going to either create an adverse side-effect or potentially, some medications may bind to the other'' rendering it therapeutically useless. Tr. 861.

[81] This specific category was explained by the witness to typically be presented as a miss-fill on the part of the pharmacist or a scrivener's error on the part of the prescriber. Tr. 868.

[82] Dr. Buffington differentiated between abuse and misuse by explaining that ''abuse could have the ill intent to produce some effect . . . that that medication has,'' while ''[m]isuse may in fact be that the individual is not taking the medication properly, so poor compliance.'' Tr. 870.

[83] Regarding Patient JM, Dr. Buffington testified that the customer-patient receiving Restoril and Xanax at the same time ''would not present a problem that needed resolved, unless, in fact, in the dialogue and counseling with that patient, you've identified a clinical concern where the patient is expressing they're not getting therapeutic benefit or possibly too much therapeutic benefit.'' Tr. 856.

entirely explained how he reached this supposition, Dr. Buffington testified that it was his understanding that each of the prescribers associated with the Ten Patients was a pain management specialist. Tr. 867. Whether this was the case or not, or how heavily this factor may have weighed into his metric, this assumption appears to have [impacted] his analysis. For each category, Dr. Buffington testified that a showing or ''hit'' of one of these categories simply requires an evaluation on whether the patient is experiencing complications or side-effects, and the absence of complications or side-effects means the ''hit'' does not rise to the level of a clinical problem. Tr. 855–58, 860, 862–63, 865, 870. The witness testified that ''[t]hese are categories that the Board of Pharmacy is saying you should evaluate these issues [sic] and determine in your professional judgment if there is something to avoid or resolve and that's the issue.'' Tr. 862. When Dr. Buffington was asked whether the presence of an opioid and a benzodiazepine would present a drug-drug interaction DUR, he replied in the following confusing way:

> No. Because those two are used routinely together. Now, could you—in other words there's no certainty that that software system is going to flag the two of those—that's something that the practitioner will understand. It may, based on the vendor who made the software or the pharmacy who added an additional manual edit to be part of that process, but none of these are hard stops with any regulatory oversight.

Tr. 862. In specifically addressing duplicate therapy in regards to Patient JM, Dr. Buffington provided, ''The mere presence of the two together do[es] not create the red flag. It's as though someone is creating or propagating the fact that if the two appear, materialize in the same regiment that it is wrong. It is not wrong unless problems ensue . . . .'' Tr. 968–69. The witness consistently alluded to a high level of deference and prerogative left, at least in his view, exclusively (and apparently un-reviewably) to the dispensing pharmacist, when he explained that for any of the categories, documentation is required only if an issue is identified (by the pharmacist). Tr. 866.

As discussed, *supra,* a recurrent theme in the testimony of this witness was to eschew the issue at hand and substitute an issue he would prefer to address. At one point during his testimony, the witness was asked whether ''patient questionnaires that were presented by [the Respondent] to new patrons . . . [is] something that [pharmacies are] required to maintain by any statute or regulation.'' Tr. 851–52. Dr. Buffington's answer was ''No, just routine practice.'' Tr. 852. Unanswered by the expert here is whether patient questionnaires are required to meet the applicable standard of care as subsumed by both federal and state statutes and regulations, and/or whether the ''routine practice'' employed by Florida pharmacies in his estimation comprises any portion of the applicable standard of care. Similarly, when asked whether there is a requirement for Florida pharmacists to document resolution of over-utilization, under-utilization, therapeutic duplication, and drug-disease contraindications, the witness's answer again injected an intentional level of equivocation:

> Only if you in the course of, normal course of your practice identified there was an issue, a clinical presentation, a concern, something that might be hindering medication compliance and the likes, then, upon recognizing those, if it's a concern during your evaluation, then you could take the steps to avoid and resolve the problem.

Tr. 866. The framework of the witness's answer here, like many of his answers, was unhelpful, and seemingly deliberately so. A red flag indicating a potential diversion issue *is* ''a concern'' or ''an issue,'' or even ''something that might be hindering medication compliance and the likes.'' [84] Thus, the interpretation that nothing is required of the pharmacist upon encountering a red flag creates an unhelpful level of a sort of plausible deniability. Another example of this is apparent in the witness's explanation of subsection (1)(g) of rule 64B16–27.810 of the Florida Administrative Code (Florida DUR Statute), which requires the identification of ''[c]linical abuse/misuse.'' Although the statute supplies no limitation regarding the nature of clinical abuse/misuse, the Respondent's expert explained this aspect of the operation of the Florida DUR Statute in this circuitous manner:

> That means if you've identified as a practitioner that the patient is abusing or misusing the medication, and we state it that way for very specific reasons, abuse could have the ill intent to produce some effect, some main effect or side-effect, that the medication has. Misuse may in fact be that the individual is not taking the medication properly, so poor compliance.

Tr. 869–70. When juxtaposed, Dr. Buffington's dismissal of almost all red flags of potential diversion as nonissues with the pragmatic operation of his interpretation of the Florida DUR Statute is quite interesting. There are virtually no red flags that can or should motivate the pharmacist to resolve prior to dispensing a controlled substance (as opposed to declining to do so), so to the extent the pharmacist intends to fill the prescription, there is no need to contact the prescriber or discuss any issues with the patient.[85] Thus, there is no real way (perhaps short of some extreme demonstration of intoxication or other drug-seeking behavior exhibited by a customer-patient which is observed and conveyed to the pharmacist by pharmacy staff, or other equally unlikely scenario) for the pharmacist to identify abuse or misuse. The pharmacist's obligation under the Florida DUR Statute is [minimized to virtually no obligation, under Dr. Buffington's view].[86] Under an interpretation where there is no obligation to do anything beyond inexorably dispensing medications (with as substandard a software system as can be found), the pharmacy registrant [does not have a meaningful role of oversight]. [Omitted for brevity.]

In opining that the Respondent met its corresponding responsibility, the witness stated that ''corresponding responsibility is specific to that if either party, the prescriber, or the dispenser, knowingly fills a medication that is illegitimate; I saw no evidence that there was any illegitimate medications, prescriptions that were filled in this case.'' Tr. 881. Dr. Buffington made it clear that the decisions made by the pharmacist, in his view, are not amenable to review by others. To the witness, a controlled substance

[84] Tr. 866.

[85] Dr. Buffington restricts a pharmacist's obligation to ''doing a valid check on the legitimacy of the prescription in terms of having done your homework and understanding the prescriber, having done your homework and understanding the patient . . . .'' Tr. 867. There was no clarification from the witness as to what objective steps could or must be invested in ''understanding'' the patient and prescriber, or what any of that means. At another point in his testimony, the Respondent's expert explained his view that validating a prescription would include an evaluation of the scrip, the completeness of the scrip, the prescriber's authority, and whatever evaluation steps are included in the pharmacy software. Tr. 909–10. When pressed upon the issue of whether risk plays a role in the assessment, Dr. Buffington stated that ''every medication has risk'' and based his answer, not on whether a red flag is triggered by the level of risk, but whether a risk, standing alone, constitutes ''a preclusion,'' which he naturally answered in the negative. Tr. 911–12. The issue with red flags in this case, as alleged by the Government, never included a hard preclusion component, but only whether the evidence demonstrated unresolved red flags of potential diversion which remained unresolved and undocumented prior to dispensing.

[86] In responding to a hypothetical, the Respondent's expert [testified] that even if newly-issued CDC guidelines indicated that a medication at a particular dosage level could result in physical harm to the patient, he would continue to dispense based on nothing more than the prescriber's unexplained insistence. Tr. 905.

prescription becomes invalid, potentially unfillable, only when there is a ''[k]nowing that the patient was using the product inappropriately—they were abusing. Knowing that the patient was going to be handed the prescription but was misusing.'' Tr. 914. Interestingly, Dr. Buffington explained that the concept of knowing is based purely on ''professional prerogative,'' [87] that the dispensing pharmacist is ''the one that has to discern if [they] know, or have reason to know—not a third party who's evaluating that.'' Tr. 917. The witness's standard strikes as an unreviewable judgment call on the part of the dispensing pharmacist. [Dr. Buffington appears to believe] that every pharmacy registrant is possessed of essentially un-regulatable, unreviewable authority. [This position is inconsistent with the] highly-regulated field such as pharmacy and the dispensing of controlled substances.

When questioned on an objective component of the concept of knowing, Dr. Buffington explained that, in his opinion, ''[t]he Florida Board of Pharmacy defines that.'' Tr. 921. Dr. Buffington suggested at one point in his testimony that the state standard of care bears no correlation to the regulatory administration of a DEA registration. Tr. 922–23. When pressed on whether his opinion would change to any extent if the Agency had interpreted knowing in a certain way, Dr. Buffington discounted DEA's authority in this way:

> Well they don't have—the DEA doesn't have the training or the expertise, and has never provided a valid instrument that is predictively—with predictive valid—validity—that demonstrates the method they would use to discern that.

Tr. 928.

[The Chief ALJ found that Dr. Buffington was hostile to DEA as a regulator, based on Dr. Buffington's testimony that he does not believe that DEA regulations or Agency decisions inform pharmacy practice in Florida, or that Agency decisions ''even translate[] to something that is enforceable.'' Tr. 930, 947, 983. I agree with the Chief ALJ that this testimony is legally incorrect to the extent that it implies that DEA has no relevance to a pharmacist's corresponding responsibility in dispensing controlled substances. Because of DEA's role in ensuring that controlled substances are distributed only through lawful channels, and its authority to revoke or suspend DEA registrations, it is incumbent on pharmacies to be familiar with DEA decisions and create pharmacy policies that ensure that pharmacists are fulfilling their corresponding responsibility. *See Suntree Pharmacy,* 85 FR 73,753, 73,770 (2020); *see also S&S Pharmacy, Inc.,* 46 FR 13,051, 13,052 (1981). DEA publishes final orders in administrative proceedings involving doctors, pharmacies, and other DEA registrants, which provide final adjudications on the public record of DEA's expectations for current and prospective members of the registrant community regarding their obligations under the CSA, in particular how the provisions of the CSA are adjudicated in enforcement actions.] [Omitted for brevity.]

Overall, even setting aside the multiple inconsistencies, evasiveness, and views he espoused that are directly contrary to the Agency's prior decisions, Dr. Buffington's expressed antagonism for the regulatory authority vested in DEA and the Administrator undermines the weight that can be attached to his presentation. While there is no question that the witness's credentials were impressive, Dr. Buffington [presented as an advocate for Respondent rather than as an impartial expert]. That is not to say that Dr. Buffington is entirely unreliable. This witness is an experienced and well-credentialed professional. There were certainly aspects of his biographical information, the progress of his career, and even some testimony regarding dispensing in general that presented as sensible and consistent with the record. However, where Dr. Buffington's views conflict with the views expressed by Dr. Schossow, at least where her views have been deemed reliable and well-supported in this RD, it is her expert opinion that must be afforded greater weight.

Dr. Aaron Howard, Pharm.D.

The Respondent (while still represented by qualified counsel) presented the testimony of Dr. Aaron Howard, the owner and pharmacist-in-charge (PIC) of the Respondent pharmacy. The witness (Dr. Howard, the Respondent's owner, or the owner) testified that he received his Doctorate in Pharmacy in 2003 and has spent the vast majority of his career as a licensed pharmacist working as a retail pharmacist. Tr. 583–84. His experience consists of work in chain and independent pharmacies, work in a hospital pharmacy,[88] as well as opening and establishing various pharmacies (including the Respondent pharmacy in 2010). Tr. 584–89.

The Respondent, doing business under the name ''At Cost RX,'' is an independent pharmacy and the witness explained that its business model was designed ''to target patients who need prescription drugs who do not have insurance or are under insured.'' Tr. 589–90. Dr. Howard testified that the Respondent pharmacy operates a membership program wherein the majority of its customer-patients pay for their prescriptions in cash. Tr. 590–91. ''[T]hat's [its] whole niche.'' Tr. 591. According to Dr. Howard, upon paying a membership fee, a customer-patient can purchase medications at the Respondent pharmacy for prices below those found in chain pharmacies in the local area. Tr. 591. The discounted price is extended as a benefit of the membership. *Id.* The witness explained that the Respondent's discounted price system and business model is designed to target ''patients who are underserved or do[ ] not have insurance.'' Tr. 1212. The ''At Cost'' name of the pharmacy is designed to convey the Respondent's primary business objective of offering medications to its customer-patients at a discounted price. Tr. 1213. [However, there is] no evidence of record that any of the Ten Patients held memberships to this purported discount program, which renders the force of this evidence as only marginally relevant. While the Respondent employs multiple pharmacists, Dr. Howard testified that he is the owner and the only pharmacist in the organization that dispenses controlled substances. Tr. 605.

Dr. Howard outlined the Respondent's pre-dispensing processes, or drug utilization review (DUR). He testified that he is the person who conducts the DUR at the Respondent pharmacy, [89] that the procedure is conducted as the prescription is being processed, [90] and that these processes have been the subject of some level of evolution over time. Tr. 600. The owner testified that he places his initials on the prescription under review to signify that the DUR steps have been undertaken and completed. Tr. 735–37. Dr. Howard's depiction of the Respondent's DUR strikes as being strongly dependent upon queries generated by the commercial electronic software (RX30) utilized by the pharmacy.[91] Tr. 607–10, 711–13, 736, 758, 1201–02, 1213–14. The owner indicated that the RX30

[87] Tr. 915.

[88] The Respondent testified that in 2003 he worked as a clinical pharmacist at Jackson Memorial Hospital. Tr. 589.

[89] Tr. 710–11.

[90] Tr. 711.

[91] Dr. Howard testified that the Respondent pharmacy has been using RX30 software since 2010. Tr. 1169.

assists him in identifying red flags of over-utilization/under-utilization, therapeutic duplication, and drug-disease contraindication. Tr. 712. When a patient presents at the Respondent pharmacy with a controlled substance prescription, Dr. Howard testified that there are a number of steps that he progresses through to verify the validity of the prescription. Tr. 596. However, he testified that there was no set order for the functions to be completed and memorialized on the prescription.[92] Tr. 770. As initially explained by the witness, where he is unfamiliar with the prescriber, the verification process begins with consulting websites maintained by DEA and the state of Florida to ensure that the prescriber's state license and DEA registration are active and without discipline or restrictions.[93] Tr. 596–97, 600–01. The owner testified that he also reviews the specialty of the prescriber. Tr. 601.

The owner testified that he then converses with the customer-patient regarding ''basic elements, how long they've been taking the medication, why they're taking the medication, things of that nature.'' Tr. 597; *see id.* at 737. To ensure that the presented patient is the patient for whom the prescription was written, the Respondent requires the presenting patient to show a government-issued photo identification card.[94] Tr. 598–99, 737. The next step involves accessing E–FORCSE to ascertain when the patient last had a controlled substance prescription filled. Tr. 597, 736. The owner described the state E–FORCSE database as ''a great tool'' that he uses to look for evidence of patient doctor-shopping, duplicate or inappropriate therapy, as well as early refills, and that he notates the execution of a check of this system on the prescription itself.[95] Tr. 611–13. If a customer-patient is accepted by the Respondent, Dr. Howard explained that he/she will fill out a questionnaire, [96] which may prompt additional questions/conversation with the patient. Tr. 598. Strangely, although the witness claims the questionnaires have been used by the pharmacy since 2015 and are maintained indefinitely, [97] these documents were not produced by the Respondent when it was served with two successive DEA investigative subpoenas requiring, *inter alia,* production of:

> [C]omplete medication or patient medication records/profiles that the pharmacy maintains which documents any and all prescriptions filled by the pharmacy; any and all additional records documenting the steps taken to avoid or resolve any issues with the prescriptions presented by [the named customer-patients] pursuant to the requirements of the Florida Statutes and Florida Administrative Code 64B16–27.800 . . . and, any other documentation kept by the pharmacy in connection with the filling of prescriptions or providing medical treatment for these individuals, including but not limited to dispensing reports, billing records, [E–FORSCE] reports and medical records.

Gov't Ex. 2 at 1; *see* Gov't Ex. 18 at 1. That the Respondent made a choice to hold these documents back from investigators, even in the face of a subpoena, does not further the strength of its position, or its efforts to rely on these items during the course of the hearing. In fact, the adverse inference sought by the Government in this case [98] is appropriately taken here. The Agency has found it appropriate to take an adverse inference where a party has made a ''decision not to provide evidence within its control . . . .'' *Morning Star Pharmacy,* 85 FR 51,063 n.38; *see Pharmacy Doctors Enters.,* 83 FR 10,899. Accordingly, the decision to withhold the documents that were the subject of the subpoena gives rise to the inference (taken here) that the information therein would not be supportive of the Respondent's case; that is, that there was either no helpful documentation in those papers, or that the documentation reflected therein would be detrimental to the Respondent's case.

Although the owner testified that the Respondent's DUR protocol has no set order, [99] he also testified at one point that the last step in the verification process involves reaching out to the prescribing physician's office.[100] Tr. 598. Although, according to the owner, he routinely reaches out to prescribers, he conceded that he does not document the substance of those conversations. Tr. 602–03. He explained that because he is the only pharmacist at the Respondent pharmacy that dispenses controlled pain medication, he keeps this information in his head. Tr. 603–05. According to Dr. Howard, he discusses a wide range of information with the prescribing doctors, such as treatment plans, modifications, and red flags. Tr. 616. When pressed on the issue of whether anomalous information received from the prescriber ever raises a concern that triggers a decision to decline dispensing, the owner would only go so far as to say ''I have done that in the past,'' but he readily admitted that he keeps no list or other documentation concerning the occasions where that has occurred. Tr. 604–05. It is the owner's estimation that he has only run into a single prescriber that he would place in the category of suspicious to the point where the Respondent pharmacy would decline to dispense on his controlled substance prescriptions. Tr. 605. In further explaining the decision not to document prescriber concerns or keep a list of suspicious prescribers, the witness offered the following:

> No, I don't keep a list, you know, because that's an independent judgment call. You know, you can't—well, I've seen people who've gotten in trouble for saying I'm not going to fill this particular physician because of X, Y, Z. I don't think that's legal. I think you can subject yourself to legal ramifications, but my protocol, since I'm the only pharmacist there, if it's something that I don't agree with that has happened with that particular physician, I don't fill it. I don't keep a printout stating that I don't fill these particular physicians.

Tr. 604–05. Thus, the decision not to document or maintain a list of suspicious prescribers is based on the owner's concern that by documenting his analysis or the result of the pharmacy's regulatory obligation to exercise its corresponding responsibility (which he is legally obligated to do), he and/or his pharmacy would be vulnerable to some theoretical legal exposure.[101] This theoretical legal concern seems to be in some tension with the rational and non-theoretical concern that by failing to document the exercise of the pharmacy's

[92] When pressed on the steps taken in the Respondent's DUR protocol, the Respondent's owner/PIC was either unable or unwilling to explain whether the steps occur in a defined order. Tr. 1192–95. There was arguably an evasive quality to the testimonial exchange with questions answered with questions and where a clear message was conveyed that the witness was unwilling to be locked into a set order of steps in the DUR process. *Id.*

[93] After the initial check, the prescriber verification process is performed annually. Tr. 605–06. No documentation was offered to support this step. [Omitted for clarity].

[94] While Dr. Howard testified that he asks for a government photo ID to verify the identity of the customer-patient, he also volunteered that he does not know if this step is a state mandate. Tr. 599.

[95] The majority of these notations consisted of a check mark and ''PDMP'' or ''PMP.''

[96] Dr. Howard testified that the Respondent began utilizing questionnaires in 2015 and that copies of the questionnaires are maintained indefinitely at the pharmacy. Tr. 599–602, 1125.

[97] Tr. 599–602, 1125.

[98] ALJ Ex. 55 at 45.

[99] Tr. 770.

[100] At another point in his testimony, he testified that the last step was filling the prescription. Tr. 1193.

[101] No legal theory was ever offered by the Respondent to support this hypothetical concern of legal exposure for doing its job.

corresponding responsibility, the pharmacy would be subject to a sanction against its DEA registration.

According to the owner, the RX30 is useful in checking for medication conflicts, allergies, and some treatment concerns, which, unlike the corresponding responsibility outcomes and analyses, Dr. Howard claims he does document. Tr. 613–15. Further, the RX30 system automatically prints out some drug-specific information and cautionary information for each patient. Tr. 618–19. The owner testified that, in addition to the RX30-generated patient information, he interacts with and counsels ''each patient'' regularly, inquiring about side effects, efficacy, and observing any overt signs of mobility limitations. Tr. 619–20.

Regarding distance as a potential red flag, Dr. Howard testified that the extent of the Respondent's distance-curiosity extends only to the zip code supplied by the patient-customer. Tr. 635. The witness provided the following elaboration on the subject:

> I look at the patient's Florida ID and I look at the zip code. If it's within the same three-digit zip code of our location, then there's nothing for me to ask pertaining to the patient. If it doesn't, then what I do is I inquire what's the reason why they're coming to our pharmacy . . . [, to ascertain t]he specific reason why they would travel to our pharmacy[.] Is it because of the prices? Is it because, you know – that's pretty much it.

Tr. 635–36; *see also id.* at 738, 1173–74. Thus, it appears that the Respondent looks at the customer-patient's zip code,[102] and if the distance is outside the three digits of the pharmacy's location, the patient is asked whether it is the Respondent's (presumably discounted) prices that has attracted the person to make the trip.[103]

Dr. Howard presented some more specific testimony concerning the Ten Patients that are the subject of the OSC/ISO. He testified that he had some familiarity with Patient JA's medical conditions. Tr. 714–15. According to Dr. Howard he spoke to this patient every month, and discussed his ailments and medications with Patient JA's multiple treating physicians.[104] Tr. 714–716, 739, 750–51. The witness testified that through his review of a prescriber's note on the prescriptions,[105] he was aware that Patient JA had no insurance. Tr. 752–54. His representation of some patient familiarity notwithstanding, beyond being led through some of the Government-supplied prescriptions, the only litigation vehicle apparently available to discuss Patient JA's treatment was to have his (then) counsel repeatedly refresh his recollection by allowing him to peruse excluded/inadmissible pharmacy patient records as he was testifying by VTC.[106] Tr. 741–51, 755–57. Obviously, the weight that can be attached to testimony borne of the essentially ministerial act of a witness reading comments from documents that were insufficiently reliable to introduce into evidence is gravely diminished, but this evidentiary contrivance was endured at the hearing to afford the Respondent every possible measure of due process.[107]

Evidence was presented in like manner regarding his understanding of Patient EA. The Respondent's owner recalled that the customer-patient was overweight, complained of leg pain, worked as a shutter installer, and that he spoke with him monthly. Tr. 762–63. He also recalled having conversations with Patient EA's prescribing doctor. Tr. 772. The remainder of the details were furnished by refreshing the owner's recollection through Government-furnished prescriptions, OOR documents, and reviewing marks he testified that he had placed on dispensed prescriptions. Tr. 764–73, 777–90, 999–1006.

The testimony followed the same pattern regarding Patient SD. The witness testified that he conversed with this customer-patient monthly and communicated with the prescriber. Tr. 1007, 1014. The owner again tracked along with the markings on the prescriptions as a guide to the DUR (which he presented as always being completed), he examined the prescriptions supplied by the Government in its exhibits, and refreshed his recollection with OOR documents as before.[108] Tr. 1007–30.

The same general mechanics were again applied by the Respondent in addressing charged prescriptions regarding Patient LH. The witness testified that he also had monthly interactions with Patient LH, that he was familiar with his prescribing physician, that the handwritten markings on the Government-furnished prescriptions signified that he employed every step of the Respondent's DUR protocol, that he considered any and all red flags, and that he had them conclusively resolved by discussions with the customer-patient prior to dispensing. Tr. 1030–47. Regarding a drug-drug interaction flag that was presented in the OOR documents, and upon realizing that even the documents contained no articulated resolution, the witness [testified]: ''Yeah. I assessed it in my mind. There's no inter—there's no issue with him taking that medication.'' Tr. 1043. On the same red flag, when asked about how the issue was actually resolved, the witness merely added: ''The [RX30] system flags it. I flagged it in my mind that that's not a[n] issue.'' Tr. 1044. Upon a third effort to attempt to help the witness explain how the red flag might have been analyzed and resolved, the owner became visibly impatient and said ''Well I don't know how else to explain it.'' *Id.* [Omitted for brevity.] The rationale here is apparently that because he dispensed the medicine he must have resolved whatever red flags may have been connected with the transaction. Either the witness was

[102] Since no evidence was received regarding the significance of postal zip code digits, this process could not be the subject of any intelligent analysis on the issue of whether it rationally furthered the objective of identifying distance red flags concerning the customer-patients.

[103] [Omitted based on the Chief ALJ's finding that the Government did not adequately prove that long distances traveled were a red flag in this case.]

[104] The witness's memory was refreshed with an excluded exhibit (Resp't Ex. 1(ID) at 49) to relate the existence of a Patient JA questionnaire (and essentially read from it). Tr. 733–34.

[105] *See, e.g.,* Gov't Ex. 5 at 11.

[106] As discussed, *infra,* the Respondent initially offered into the record a set of Proposed Respondent Exhibits (Resp't Ex. 1(ID) at 41–90) that purportedly related to Patient JA. Although untimely, the Government's timeliness objections were overruled to afford the Respondent the maximum level of due process. Tr. 642–60. However, other fundamental issues regarding inadequate foundation and reliability precluded the admission of the tendered evidence as being sufficiently reliable to be considered in this adjudication. *See* 5 U.S.C. 556(d). It is telling that after the anomalies regarding Respondent Exhibit 1(ID) were discovered, the Respondent's (then) counsel did not seek to offer the balance of the Proposed Respondent Exhibits that related to the nine other charged customer-patients. It is reasonable to assume that the unoffered documents suffered from the same reliability issues, but as they were not offered, such an assumption or further discussion is not required. Instead, the balance of those unoffered and outside-of-record (OOR) documents were used by the Respondent to refresh the recollection of the owner for each of the Ten Patients.

[107] No attempt was made by the Respondent to seek to introduce any of the refreshing documents as past recollection recorded. *See* Fed. R. Evid. 803(5). Ironically, on the last day of his testimony, when asked about whether he even remembered his testimony being refreshed on the previous day, the owner snapped ''That was yesterday. I can't remember. What—I guess what's your question?'' and ''I don't recall yesterday, but whatever —.'' Tr. 1189. Suffice it to say that announcing under oath that he has no recollection of events occurring on the previous day is singularly unhelpful to the credibility of a witness asking the tribunal and the Agency to credit his recollection of events that occurred months and years prior.

[108] There was even a point during Dr. Howard's testimony where his counsel forgot to employ the contrivance of having his recollection refreshed and the process devolved to the witness simply reading content verbatim from the OOR documents pertaining to Patient SD into the record. Tr. 1025–27. Suffice it to say that this did not enhance the credibility and force of his testimony, or the weight to be accorded to it.

being truthful and his analysis was really no cognizable analysis, or the red flag was never really considered before the medication was dispensed. Neither scenario furthers the Respondent's interests in avoiding a registration sanction in this case. Even the subsequent leading, rehabilitation questions from the Respondent's counsel about whether he believes he ''[w]ould [ ] have filled the prescription if [the red flag] had not been resolved'' [109] [did not rehabilitate the witness on this issue].

The testimony of the Respondent's owner regarding Patient DH followed the same general configuration. There was some testimony regarding the customer-patient's diagnoses.[110] Tr. 1058. The witness's memory also was refreshed [111] using a patient questionnaire that was also not offered or admitted into the record. Tr. 1059–64. At one point during the witness's testimony about Patient DH he testified that he spoke to the prescriber to resolve a drug-drug red flag, then when pressed, retreated to the language of the refreshing document, and corrected his testimony to reflect that he only consulted with the patient on the issue. Tr. 1068–71. It is reasonable to infer that a recurring theme for this witness was to somehow ascertain the most advantageous answer, which often came from the refreshing documents.

The testimony was very much the same with respect to Patient JM. The owner averred that he saw the patient monthly, that he spoke with her prescribers, and while on the stand he had his recollection refreshed with OOR documents. Tr. 1102–35. The recognition of marks on prescriptions regarding Patient JM again allowed him to assure the tribunal that all appropriate steps were taken. Tr. 1118–19, 1129–35. One aspect that was unique to the witness's refreshed recollection regarding this patient is that, the testimony of the Government's expert notwithstanding, the owner insisted that prescribing two different benzodiazepines simultaneously to one patient is ''not a problem.'' Tr. 1111. The owner dismissed the entire issue this way: ''So I did hear previous testimony stating that that's an issue, it's absolutely incorrect.'' Tr. 1111–12. Simultaneous prescribing of multiple opioids received the same treatment from the owner. When asked if this practice raised a red flag, his answer was ''[a]bsolutely not.'' Tr. 1112. He saw no red flags that required resolution. Tr. 1116.

The owner's testimony regarding Patient JW was more of the same. He said he spoke to the patient once a month, spoke with his prescriber, and read off of a litany of OOR documents purportedly to tender a more refreshed recollection. Tr. 1139–50. Interestingly, the owner opined that the administration of methadone for pain is common. Tr. 1146. Whether through disinterest, witness fatigue, self-interest, or some other cause, when asked by counsel whether his testimony regarding the significance of the prescription annotations extended to all the prescriptions received in the record, the witness first said ''No it wouldn't,'' but upon being pointedly re-asked the same question by the Respondent's counsel, the witness then agreed that it would. Tr. 1148–49. This seeming recurrence of the witness's willingness to say whatever answer he believed would be most helpful to his cause was not a credibility-enhancing feature of his presentation. Sworn testimony where a witness definitively responds yes and then upon being abruptly asked the same question a second time responds no hardly presents a model for reliable evidence.

The same pattern persisted regarding the witness's testimony concerning Patient CW. More refreshing that followed seemingly rote assurances that the customer-patient was seen monthly, and a blanket statement that no concerns regarding the dispensing events were encountered.[112] Tr. 1151–64. Tellingly, when asked by the Respondent's counsel whether the owner specifically recalled any physical observations regarding Patient CW, the witness replied:

> Well, yeah. I mean, I've been knowing her for probably since 2012, so I can't remember like right off the top of my head, right now, as far as—I can't remember right of the top of my head. I'm not sure.

Tr. 1152. Thus, when first asked, the witness responded that he did recall some physical observations about the customer-patient, but then, apparently realizing that he might be called upon to relate some of those observations, reversed course and said he was not sure and could not remember them ''off the top of [his] head.'' *Id.* Prescribing multiple opioids simultaneously also was, in the opinion of the owner, undeserving of any particular heightened scrutiny. Tr. 1156. The witness's view of disregarding the Government expert's view regarding this red flag was merely that the patient-customer had ''been on pain management therapy for a very, very long time that I can remember . . . [for] a lot of different ailments . . . .'' *Id.* Thus, the owner's account presents a binary choice: Either there is no red flag inherent in prescribing multiple opioids and the Government's expert is wrong, or the mere fact that the patient has been receiving medications in the face of a long-term unresolved red flag of potential diversion is completely dissipated by the fact that the dispensing (from the Respondent pharmacy) has been conducted in this manner for a long time. Neither scenario is particularly persuasive. The testimony of the Government's expert regarding the validity of this multiple-opioid red flag is persuasive, and the fact that a red flag was ignored for a sustained period does not deprive the red flag of its soundness.

The presentation pattern was substantially repeated regarding Patient DK. Tr. 1078–1101. The witness did convey some seemingly contemporaneous memory about Patient DK, remembering some particulars about her treatment and about the fact that (according to the owner) a caretaker regularly dropped her off to retrieve her medications. Tr. 1086–88. But the Respondent resorted to the same recollection refreshing regarding the significant particulars of the dispensing events. One feature of the owner's testimony regarding Patient DK was particularly telling. When directed to one of the Government-furnished prescriptions issued to this patient, the Respondent's counsel invited his attention to what appeared to be a seemingly commendable notation on the prescription that purportedly synopsized a conversation between the owner and Patient DK concerning her diagnoses, weight loss, and pain

[109] Tr. 1045.

[110] [Omitted for brevity.]

[111] Even though this process had repeated itself numerous times, when asked by his counsel whether he had ''an independent recollection of the flags that were raised and resolved with respect to the first set of prescriptions that [he had been asked] about with [Patient] DH,'' he answered that he did. Tr. 1066. Thus, it would have appeared that the witness's memory was not in need of refreshing. When asked about it, the witness then immediately said ''No, I don't recall.'' *Id.* Like many other features of this witness's testimony, this feature did not enhance the credibility of his presentation. This additional anomaly notwithstanding, the Respondent's counsel was permitted to continue to refresh the owner's recollection with excluded documentation to afford the Respondent the maximum margin of due process.

[112] The witness testified that he did see a PMP anomaly regarding a new prescriber, raising a conflict that he purportedly resolved through conversations with the customer-patient and the prescriber, some details of which were memorialized in a July 31, 2019 handwritten note on the applicable prescription. Tr. 1163–64; Gov't Ex. 29 at 5.

level.[113] Gov't Ex. 26 at 17–18. After identifying his handwriting, the witness [offered testimony that devalued the importance of documentation]:

> Q. Dr. Howard, can you please tell the tribunal what was the intent and purpose of the note that you placed on this particular prescription?
>
> A. Basically, to document the conversations between the patients more. With this situation, what occurred is the patient had been in the hospital for probably about three weeks from a serious infection and what happened was is [that] the physician reduced the dosage for the patient based upon her weight loss. So I counseled the patient and explained to her the reason why the physician reduced her medication based upon that issue. So that was the reason why I documented it, it's just an extra compliance step. This is something that pharmacists do all the time, never to—*never to thought to this point where you would have to do things like this,* but this is what we do.
>
> Q. I'm sorry, when you say you never thought you had to do things like this, what did you mean by this?
>
> A. Document to this extent. I mean it's just—*it's absolutely absurd* because you would be doing more documenting than dispensing medication if you go by some of the previous testimonies that I've heard, being a pharmacist.
>
> Q. Let me stop you there. . . .

Tr. 1095–96 (emphasis supplied). When invited multiple times (by the tribunal and the Respondent's counsel) to explain what he meant about the documentation being ''absurd,'' the Respondent's owner stuck to his guns on the issue. Tr. 1098–1100. The owner asked the tribunal whether he had ever worked in a pharmacy, and upon procuring a negative response, he offered the following:

> Okay. So if you've ever worked in a pharmacy, you have a lot of patient interaction between yourself and the patient. And you have conversations every month. If you were to document every conversation, every incident that you have with a particular patient, you would not be able to fill prescriptions.

Tr. 1098. When invited again to explain the part of the documentation obligation that he found ''absurd,'' the Respondent's owner doubled down, stating:

> Well, I mean I think it's absurd to the sense where from testimony that I've heard, previous testimony that I've heard on you call a physician every time you almost fill a prescription or if you know that particular patient, you know their illness. You've had interaction with that patient over the years. To call a physician, and you know the physician and you know the patient, on every prescription is absurd.

Tr. 1099. The only testimony the Respondent's owner ''heard'' during the hearing on this subject emanated from the Government's expert witness, but to remove any ambiguity on that front, the witness clarified that the testimony he was referring to as ''absurd'' was ''the expert witness for the DEA.'' Tr. 1100. Thus, the Respondent's owner was making it clear that the documentation requirements that underpin the standard of care are absurd in his view. [Omitted for brevity. I agree with the Chief ALJ that Respondent's statements as do not instill confidence in me that he will be compliant with the law in the future.]

At one point during the witness's testimony, the Government conducted a *voir dire* regarding screen shots of RX30 pages (the RX30 Screen Shots) regarding Patient JA that were purportedly generated in the ordinary course of business in the Respondent pharmacy at the time of the charged dispensing events.[114] Resp't Ex. 1(ID) at 55–90. Although the Government's timeliness objections were overruled, the Respondent, as the proponent of the evidence,[115] was ultimately unsuccessful in bearing its burden to establish admissibility. The Respondent's theory for admission of the RX30 Screen Shots was founded on the proposition that each tendered page was a screen shot of information created and inputted into the RX30 at the time of the dispensing event. Tr. 664–69. Dr. Howard testified that he created and prepared every one of the documents within the RX30 Screen Shots. Tr. 669, 686–88. At one point he testified that the data entries were made either by himself or the pharmacy staff. Tr. 665. He also (inconsistently) said that he inputted all data into the system himself. Tr. 688. However, the witness was unequivocal that the screen shots in question were made by him personally. Tr. 687–88. Yet, when Dr. Howard was asked to explain, if he truly made all the RX30 entries, why various RX30 screens contained the initials of pharmacy techs who work at his pharmacy, his answers were [inconsistent and confusing]. The witness first said that the tech initials could be explained by ''[i]t could've been a different screen that I had to open up, or something like that.'' Tr. 686. After an offer by Dr. Howard to ''clarify so I can let you understand,'' he explained the presence of various tech initials by saying, ''That means that when I was logged into the system, I was logged in under just my initials.'' *Id.* When asked why some of the initial fields were blank, the Respondent offered that this was ''[b]ecause I was logged into my system.'' Tr. 687. When pressed on this and given another opportunity to explain, the owner stated that the initials from various pharmacy technicians appeared on the screens on different pages

> [b]ecause I didn't generate them all in one day. I didn't sit there and go through these all in one day . . . . I just explained to you. Because when those would generate [sic], it was under that tech's—I guess, that computer.

Tr. 687. Whether the data was all inputted by Dr. Howard (as he said) or by Dr. Howard and pharmacy staff (which he also said), it is clear that this is yet another issue upon which Dr. Howard has provided inconsistent information under oath. Obviously, when taken together, none of these explanatory statements (made by a highly educated medical professional) made any sense whatsoever, raising the reasonable inference that he was being less than candid about the RX30 system, the identity of those who entered the data, and (most importantly) the integrity of the proffered evidence.

Although the overwhelming majority of the tendered RX30 Screen Shots had a ''Print'' option at the bottom of the page, the owner at one point testified that the pages could not, in fact, be printed. Tr. 672. Dr. Howard then stated that the pages could be printed so long as the print feature is accessed through the DUR screen related to a specific dispensing event. Tr. 672. He then reversed himself and adhered to his initial position that the screen could not be printed out. Tr. 673.

The majority of these pages contained options for a variety of actions, *to wit:* ''F1 Return,'' ''F3 Select,'' ''F5 Print,'' ''F8 Delete,'' and ''F9 Help.'' Resp't Ex. 1(ID) at 57–66, 68–90. Notwithstanding Dr. Howard's assurance that the pages could not be printed, the majority of the software pages he tendered for the

[113] The witness testified that the conversation with the customer-patient led to a resolved understanding of the prescriber's decision to titrate the customer-patient's medication downward. Tr. 1097.

[114] As it happens, these documents were not timely served on the tribunal or the Government, and the Government's timeliness objections were overruled to afford the Respondent the maximum level of due process. Tr. 642–60. However, other fundamental issues regarding foundation and reliability precluded the admission of the tendered evidence as being sufficiently reliable to be considered in this adjudication. *See* 5 U.S.C. 556(d). While the procedural timeliness objection could be (and was) overlooked by the tribunal in an effort to ensure the Respondent was able to present its case, the inherent unreliability of the tendered documents (as discussed, *infra*) prevented receipt into the record.

[115] *See* 5 U.S.C. 556(d). The untimely filing of the proposed evidence in the absence of any demonstration of good cause supplied good cause for the Government's at-hearing authenticity objection. *See* 21 CFR 1316.59(c).

record clearly contained a print option for the operator on the screen. Page 67 of the RX30 Screen Shots (Page 67) had no option to print, but unlike any of the other pages, this page had a ''F4 Save'' option, which was clearly highlighted. *Id.* at 67. It is not unreasonable to infer that the appearance of a ''Save'' option that was unique to a single page signals that as yet unsaved information was entered or altered into the database and that this changed information is now amenable to being saved. In the absence of any explanation by the owner (the purportedly most knowledgeable person at the hearing about the RX30 system) to the contrary, the preponderant evidence supports the proposition that Page 67 in the proffered exhibit depicts data that was altered or supplemented prior to the printing of the page, and not when the dispensing event occurred. Another feature that was remarkable about the RX30 Screen Shots is that, notwithstanding the Respondent's admission theory that these documents represent unadulterated screen shots that merely and reliably depict information stored in the RX30 system, the cursor is lit up on different fields depending on the page. *Id.* at 57, 63, 66, 68–90 (Intervention field), 58–62, 64–65 (Outcome field), 67 (Reason for Intervention field), 56 (Patient name field), 55 (a listed diagnosis within the International Classification of Diseases (ICD) field). When asked why the cursor was resting in different fields depending on the page, the owner dismissively declared that he did not know, that he had ''no clue,'' that he had ''no idea,'' and that ''[i]f you're trying to imply that I changed things, you're wrong.'' Tr. 675–78, 682–83. This was one of the points during the hearing where the witness's voice and demeanor reflected increasing agitation and volume as the inquiry progressed.

The witness insisted that he did not know where the cursor ordinarily populates and was unable to explain why it migrated to different places on the RX30 Screen Shots.[116] Tr. 671. Additionally, when asked why one of the pages contained text that bore a date about three and a half years beyond the dispensing event date,[117] the witness was unable to explain, but just kept repeating that he did not understand the question, and defensively asked ''what are you trying to say?'' Tr. 670–71, 679, 681–82.

Dr. Howard's contradictory and illogical statements, coupled with his dismissive declarations that he has no clue and no idea about how his own software system operates and why a host of anomalies were present in the tendered RX30 Screen Shots, were and are simply unpersuasive and detracted profoundly, not only from the Respondent's attempts to secure admission of the evidence, but more fundamentally from any credibility that could be accorded to the balance of his sworn testimony.

The dynamic regarding the RX30 notes is rendered worse by the fact that, as discussed, *supra,* these purportedly contemporaneously-created notes fit squarely within the parameters of the DEA's multiple subpoena demands for:

> [C]omplete medication or patient medication records/profiles that the pharmacy maintains which documents any and all prescriptions filled by the pharmacy; any and all additional records documenting the steps taken to avoid or resolve any issues with the prescriptions presented by [the named customer-patients] pursuant to the requirements of the Florida Statutes and Florida Administrative Code 64B16–27.800 . . . and, any other documentation kept by the pharmacy in connection with the filling of prescriptions or providing medical treatment for these individuals, including but not limited to dispensing reports, billing records, [E–FORSCE] reports and medical records.

Gov't Ex. 2 at 1; *see* Gov't Ex. 18 at 1. The Respondent's owner [testified that he was confused by what was required]. Tr. 1206–07. The Respondent's owner is and was a highly-educated, experienced registrant. The idea that this clear, directive language [was too confusing for him to comply with the subpoena was not credible]. Similarly unpersuasive was the Respondent's argument that the owner was unobligated to comply with the Government's multiple subpoenas because they were addressed to his counsel.[118] Tr. 1208. The issue here was not a subpoena enforcement technicality being litigated in a United States District Court. *See* 5 U.S.C. 555(d). The Respondent is engaged in a dangerous, highly-regulated activity, and it and its (then) counsel well understood the documents the regulator was seeking. Likewise, the owner's preliminary response to whether he produced the customer-patient questionnaires that evolved from ''I think, at that time I think it was [produced], I believe so,'' to a solid declaration that in the course of several seconds of testimony that he somehow became sure that the questionnaires were provided, was unconvincing to say the least. Tr. 1168–73. Similarly, when asked in what format the questionnaires were supplied to the Government, and if they were supplied in hard copy, the witness first said, ''I'm not sure. I would assume. Yeah, they were in hard—well I don't know if they were in hard copy, but I, I guess they were sent electronically.'' Tr. 1172. This was shortly followed up by this more definitive declaration: ''Electronically. We produced them electronically.'' Tr. 1173. This was immediately followed by the following statement:

> To be honest with you, I don't 100% know. I know that we provided them to you. You know, whatever question that you're trying to get at, I can tell you that we provided them to them, to you. Now the means that we provided it to you, I cannot remember, so I don't want to sit here and say something that I did or didn't do, when I totally don't remember. I can tell you we scanned them. They were in a binder, we scanned them in, and those were provided to you.

Id. [This testimony was inconsistent and not credible. Omitted for brevity.] The questionnaires and the RX30 notes were not produced when demanded. They were produced late and with anomalies in the RX30 notes that precluded a finding that they were reliable and may even possibly have been altered; and notwithstanding all that, the witness was still permitted to have his recollections refreshed by mostly reading the content of the unreliable, untimely-filed documents. The inconsistency of the owner's

[116] Notwithstanding his testimony that he inputted all the information into the RX30 system, the owner did not seem to understand much about how the system actually works; and his lack of understanding extended beyond cursors and printing. At another point in his testimony, Dr. Howard testified that he was unsure if the customer-patients were presented with counseling screens at the time of medication dispensing. Tr. 758–59. When asked about it, he simply said ''I'm not aware of how it works.'' Tr. 758. Ultimately, he gave up on explaining whether the RX30 had such a feature, and volunteered that he provides a hardcopy paper counseling election sheet to each patient. Tr. 759. But when asked where such hardcopy counseling sheets are maintained at the pharmacy, he was unable to supply a coherent response. When asked if the counseling sheets are kept in a binder, his answer was: ''Well, it's not a binder. We keep it sort of—well, yeah, it's a binder.'' Tr. 760. The same confusion permeated the owner's testimony about other systems that he would have been expected to be conversant in. When asked about whether and where patient questionnaires are maintained and for how long, he testified that they were stored at the pharmacy, and joked that they were maintained ''[a]s long as we don't lose them.'' Tr. 601–03. Inasmuch as he testified that he is the owner, PIC, and exclusive controlled substance dispensing pharmacist, his general lack of awareness about the automation system utilized by his pharmacy, and even other filing systems used there, is surprising. Irrespective of whether the witness was being intentionally evasive, or genuinely lacks a basis for understanding the pharmacy systems (automated and manual) operating under the pharmacy he owns and supervises, this feature of his presentation was unhelpful in meeting the Government's evidence.

[117] Resp't Ex. 1(ID) at 57.

[118] Tr. 1215.

answers, the structure of the Respondent's actions in subpoena (non)compliance, and the refreshing use of the documents essentially precluded reasonable reliance on these late-discovered items and ultimately hurt the credibility of the Respondent's case.

At another point in the owner's testimony, when asked the basic, straightforward question as to whether he ''would agree that there are red flags in pharmacy,'' the witness supplied the following convoluted response:

> Well if you want to deem it as a red flag, if you want to use the term red flag, that will be considered a red flag, or, if you check the PMP and you see that this patient that probably has a valid prescription but they went to two other physicians the day before, that's a red flag, for the same medication, those—if you wanna use the term red flag, that's a red flag.

Tr. 1182–83. While the witness did indicate that he would not dispense a prescription under the scenario his own reply created, his answer was [concerning in that he remains unwilling to acknowledge the importance, or even existence, of red flags. He dismissed the concept of a red flag] as a subjective exercise in whether the questioner (*i.e.,* DEA) ''want[s] to deem it as a red flag,'' whereby anything ''will be considered a red flag.'' Tr. 1182. [Omitted for brevity. I agree with the Chief ALJ that these statements do not instill confidence in me that Respondent will be compliant with the law in the future.]

The Respondent's owner supplied another insightful window into his true amenability to regulatory oversight at another point in his testimony. This exchange commenced with an inquiry regarding whether the questionnaires used by the pharmacy had seen any level of modification over time. The owner impatiently replied that the documents were modified in format for ''[t]he same reason why we're sitting here.'' Tr. 1185. When asked to explain, the witness [testified]:

> All the documentation and things that we try to do to satisfy the DEA, it still does not matter, all the documentation, all the compliance that we've done, to show regulatory agencies we go over and beyond to try to, to make sure that we do our part, it did not matter. It did not matter. . . . I said it does not matter to the regulatory agencies. It does not matter as far as how much compliance the pharmacy does. We [changed the questionnaire] as a compliance issue to make sure that we're trying to stay in compliance. We asked for guidance. We try our best to do what's right.

Tr. 1185–86. Thus, even in this case where the record shows that the Respondent's documentation was inadequate [and outside the usual course of professional practice], the owner's response is that he believes he has done enough and it does not matter what steps his pharmacy takes in the future. This is not the voice of a registrant seeking to come into compliance, but essentially one who is communicating that he is [frustrated] with the efforts already invested to try to meet the state standards for dispensing controlled substances. The owner's mindset remained consistent when asked about why the Respondent's patient questionnaires queried about distance. The witness did not indicate that distance could be an important red flag of potential diversion, but rather affirmed that the question was included ''[b]ecause that's one of the things that the DEA has been targeting, is patients traveling long distances.'' Tr. 1218. [Omitted for brevity.]

The witness was also unwilling to distance himself from Dr. Buffington's opinions that DEA has virtually no legitimate role in regulating the dispensing of controlled substances, notwithstanding invitations by the tribunal to do so in the best interests of his case. Tr. 1222–24. [The witness maintained throughout the hearing] that every single prescription that is the subject of these proceedings was dispensed correctly and with adequate documentation. Tr. 1224.

On the issue of credibility, Respondent's owner, Dr. Howard, has the most at stake in these proceedings, as the DEA registration that is the subject of this litigation concerns his pharmacy. Even beyond that, the testimony of this witness was often evasive, internally inconsistent, defensive, implausible, and sometimes even objectively hostile in tone.[119] As discussed in considerable detail, *supra,* during the course of his testimony, the witness [stated] that many of the efforts expended in the Respondent's dispensing practices were not geared toward identifying and targeting potential diversion, but to avoid professional scrutiny from DEA. [Additionally], the fact that the Respondent's owner declined to turn over subpoenaed documents until late in the proceedings, and sponsored documents that raised anomalies that were fatal to their reception into the record, further undermined his credibility, resulted in an adverse inference, and diluted the strength of his case. As discussed, *supra,* the Respondent's owner [declined] to distance himself from the testimony of its expert witness that DEA [does not have a significant role] in regulating pharmacy practice. To be sure, there were certain historical and/or biographical features of this witness's testimony that could be credited, but regrettably, the testimony presented by this witness cannot be afforded a positive credibility finding.

Other facts necessary for a disposition of this case are set forth in the balance of this recommended decision.

[119] Even beyond the words on the page of a sterile transcript (quite animated, even on their own in this case), the witness's tone and volume during his testimony was sometimes elevated and presented on multiple occasions as impatient and even visibly angry.

The Analysis

The Government seeks revocation based on its contention that the Respondent, through its pharmacists and employees, has committed acts that would render its continued registration inconsistent with the public interest as provided in 21 U.S.C. 823(f). The gravamen of the Government's allegations and evidence in this case focus on the Respondent's alleged (1) dereliction in the exercise of its corresponding responsibility in dispensing of controlled substance prescriptions and (2) violations of federal and state laws relating to controlled substances.

Public Interest Determination: The Standard

Under 21 U.S.C. 824(a)(4), the Agency may revoke the COR of a registrant if the registrant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Congress has circumscribed the definition of public interest in this context by directing consideration of the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

''These factors are to be considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in

determining whether a registrant's COR should be revoked. *Id.; see Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall,* 412 F.3d at 173–74), and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In the adjudication of a revocation of a DEA COR, DEA has the burden of proving that the requirements for the revocation it seeks are satisfied. 21 CFR 1301.44(e). Where the Government has met this burden by making a *prima facie* case for revocation of a registrant's COR, the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Further, ''to rebut the Government's *prima facie* case, [a respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *accord Krishna-Iyer,* 74 FR 464 n.8. In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38,363, 38,364, 38385 (2013).

Normal hardships to the registrant, and even the surrounding community, which are attendant upon lack of registration, are not a relevant consideration. *Heavenly Care Pharmacy,* 85 FR 53,402, 53,420 (2020) (principle conclusively applied to pharmacy registrants); *Linda Sue Cheek, M.D.,* 76 FR 66,972, 66,972–73 (2011); *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,757 (2009). Further, the Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that future misconduct will not occur. *Hoxie,* 419 F.3d at 483.[120]

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–03 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by ''substantial evidence,'' *Hoxie,* 419 F.3d at 481. While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989) (citation omitted), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered, *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *see Humphreys* v. *DEA,* 96 F.3d 658, 663 (3d Cir. 1996). [Omitted for brevity.]

[Omitted for brevity.] It is well settled that, because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *see Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Agency's final decision, *see Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. *See* 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a)(1947).

[120] The Agency has consistently adhered to this policy in its adjudications. *See, e.g., Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (holding that the respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66,138, 66,140, 66,145, 66,148 (2010); *George C. Aycock, M.D.,* 74 FR 17,529, 17,543 (2009); *Krishna-Iyer,* 74 FR 463; *Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078 (2009); *Med. Shoppe-Jonesborough,* 73 FR 387.

Factors Two and Four: The Respondent's Experience Dispensing Controlled Substances and Compliance With Federal, State, and Local Law

The Government has founded its theory for sanction exclusively on Public Interest Factors Two and Four, and it is to those two factors that the evidence of record relates.[121]

Applying the record evidence to Factor Two (experience in dispensing controlled substances) in accordance with Agency precedent,[122] the Respondent is owned by Dr. Howard, and has been licensed in Florida since 2010. Tr. 584. No evidence was introduced regarding the length of time

[121] The record contains no recommendation from any state licensing board or professional disciplinary authority (Factor One). [Where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011) (''The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'').] The record likewise contains no evidence of a specific recommendation by competent state authority or any action from which its intent could be discerned. *See Jeanne E. Germeil, M.D.,* 85 FR 73,786, 73,799 (2020) (Agency recognizes that its prior final orders have considered this dichotomy of sources for Factor One consideration). The Agency has recognized that the failure by a state to affirmatively take action against a registrant ''carries minimal to no weight under Factor One.'' *Id.* Similarly, there is no record evidence of a conviction record relating to regulated activity (Factor Three). Even apart from the fact that the plain language of this factor does not appear to place emphasis on the absence of such a conviction record, the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities lessen the logical impact of the absence of such a record. *See Robert L. Dougherty, M.D.,* 76 FR 16,823, 16,833 n.13 (2011); *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.''), *aff'd, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057 n.2 (2009). The Agency has previously recognized the minimal impact of the absence of such a conviction in the Public Interest analysis. *Germeil,* 85 FR 73,799. Therefore, the absence of criminal convictions militates neither for nor against the revocation sought by the Government. That the Government's allegations and evidence fit squarely within the parameters of Factors Two and Four and do not raise ''*other* conduct which may threaten the public health and safety,'' 21 U.S.C. 823(f)(5) (Factor Five) (emphasis supplied), likewise militates neither for nor against the sanction sought by the Government in this case.

[122] *JM Pharmacy Grp., Inc.,* 80 FR 28,667, 28,667 n.2 (2015); *Krishna-Iyer,* 74 FR 462.

that the Respondent pharmacy has been in operation or any basis upon which to characterize its level of compliance prior to the allegations that form the basis of this litigation.

The lion's share of the evidence presented in this litigation is most readily considered under Factor Four (compliance with laws related to controlled substances). To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Under the regulations, ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a). [Omitted.] *F

The pharmacy registrant's responsibility under the regulations is not coextensive or identical to the duties imposed upon a prescriber, but rather, it is a *corresponding* one. 21 CFR 1306.04(a). The regulation does not require the pharmacist to practice medicine; it instead imposes the responsibility to decline to dispense based upon an order that purports to be a prescription, but may not be, because evidence (either apparent on the prescription or attendant to the presentation of that scrip) would lead a reasonable pharmacist to suspect that the practitioner issued the prescription outside the scope of legitimate medical practice. *E. Main St. Pharmacy,* 75 FR 66,149, 66,157 n.30 (2010). [Omitted.] *G

[According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

> An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. ''The language in 21 CFR 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing United *States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

To prove a pharmacist violated her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28,667, 28,670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR 62,341 (citing *Med. Shoppe—Jonesborough,* 73 FR 384; *United Prescription Servs., Inc.,* 72 FR 50,397, 50,407–08 (2007); *EZRX, L.L.C.,* 69 FR 63,178, 63,181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61,613, 61,617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64,921, 64,924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR 63,181; *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR 62,341.

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation for each of the patients at issue in this matter by filling prescriptions without addressing or resolving multiple red flags of abuse or diversion. Agency decisions have consistently found that prescriptions with the similar red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,898, *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash

*F Omitted to reduce repetition with added text. *See infra* n. *H.

*G Omitted to reduce repetition with added text. *See infra* n. *H.

payments; early refills); *Hills Pharmacy,* 81 FR 49,816, 49,836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62,316, 62,317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Here, the Government established the presence of red flags on the prescriptions that Respondent pharmacy filled.][*H]

The Florida Administrative Code requires pharmacists to conduct a prospective drug use review for each ''new and refill prescription presented for dispensing'' and identify, *inter alia,* ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''[d]rug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code Ann. r. 64B16–27.810(1) (Florida DUR Statute). Under the Florida DUR Statute, if such a matter is identified, ''the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'' *Id.* r. 64B16–27.810(2). A patient record system is required to be maintained in order to ''provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing.'' Fla. Admin. Code Ann. r. 64B16–27.800(1). Significantly, within the patient record, a ''pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain'' information including, *inter alia,* ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* In regard to controlled substance prescriptions, under the Florida Pharmacy Standards Statute, a pharmacist in Florida must ''exercise[e] sound professional judgment'' in filling controlled substance prescriptions and ''shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' Fla. Admin. Code Ann. r. 64B16–27.831. Specifically, ''when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.'' *Id.* r. 64B16–27.831(2). A valid prescription for a controlled substance is defined as one ''based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose,'' while an invalid prescription is one ''the pharmacist knows or has reason to know that . . . was not issued for a legitimate medical purpose.'' *Id.* r. 64B16–27.831(1)(a), (b). As discussed, *supra,* the concept of red flags is encapsulated in the FPSS as ''circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance.'' *Id.* r. 64B16–27.831(2). Upon encountering a ''circumstance that may cause a pharmacist to question the validity of a prescription for a controlled substance'' (*i.e.,* a red flag of potential diversion), a Florida pharmacist must reach out to either the prescriber or the patient; and where appropriate, in place of one of those two sources (but not both) the pharmacist may resolve a red flag by an E–FORCSE query. The Florida Pharmacy Patient Record Statute directs that ''[t]he pharmacist shall record any related information indicated by a licensed health care practitioner.'' Fla. Admin. Code Ann. r. 64B16–27.800(2). The FPPRS also directs pharmacists to create a record of ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* r. 64B16–27.800(1)(f). Accordingly the substance of the contacts initiated by a Florida pharmacist to resolve encountered red flags (which is required) must be documented.[*I] A failure to follow up on the red flags and the failure to document that follow-up falls below the applicable standard of care.

Here,[123] the Government has alleged and presented evidence that the

[*H] The supplemented text in this section clarifies my analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

[*I] As explained above, *see supra* n. *E, I agree with the Chief ALJ's conclusion that Florida law requires pharmacists to document their attempts to address and resolve red flags. However, my Decision does not rely on any interpretation of Florida law, because, in failing to document the resolution of red flags, Respondent violated federal law in addition to state law. *See* 21 CFR 1306.04(a) and 1306.06. Respondent's violations of federal law serve as an independent basis for my conclusion that Respondent's registration is inconsistent with the public interest and that revocation is the appropriate remedy in this case.

[123] As discussed, *supra,* the CSA authorizes the Agency to impose a sanction upon a finding that a registrant ''has committed such acts as would render [its] registration under [21 U.S.C. 823] inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Thus, for the Government to satisfy its *prima facie* burden, it must allege facts that, if sustained, would actually demonstrate that the registrant committed such acts as would render its registration inconsistent with the public interest. *See id.* Here, in a subset of allegations relating to the Ten Patients (the She-Opined Allegations), the Government does not allege actions, conduct, or omissions attributable to the Respondent, but rather conclusions or observations made by its own pharmacy expert. ALJ Ex. 1 ¶¶ 5, 6, 8, 9, 10, 11, 12, 13. The plain language of each of the She-Opined Allegations points merely to the fact that (at some unspecified point in time) the Government's expert concluded that certain matters were true. Even if preponderantly established by the evidence, the fact that the Government's expert held a point of view on a fact (in the past or at any time) cannot and does not constitute evidence (or, as more relevant here, an allegation) that the Respondent engaged in acts that are inconsistent with the public interest. However, while the drafting of the She-Opined Allegations is certainly suboptimal, it is clear that these issues were litigated by consent. *See Farmacia Yani,* 80 FR 29,053, 29,059 (2015); *Grider Drug #1 and Grider Drug #2,* 77 FR 44,070, 44,078 n.23 (2012). The parties mutually understood that they were litigating the issue of whether the controlled-substance dispensing issues set forth in a subset of those allegations depicted conduct that fell below the applicable standard. Additionally, this issue was not raised by the Respondent in its closing brief. *See* ALJ Ex. 54. This case raises no realistic notice issues, and the OSC/ISO language related to the opinions of the Government's expert will be treated here as surplusage that does not impact the validity of the charges or the findings. Accordingly, based on the conduct of the parties at the hearing, as well as their post-hearing briefs, the She-Opined Allegations will be considered as if the underlying actions are alleged, not as if the conclusions of the Government's expert (at some unspecified time) are the single issue (that is: As they were drafted and served on the Respondent and this tribunal). [Furthermore, it is noted that the OSC/ISO did include overarching acts or omissions in addition to the more-specific expert opinions. The OSC/ISO states that Respondent repeatedly filled prescriptions without addressing and resolving obvious red flags of drug abuse and diversion, which is conduct that constitutes ''acts [that] would render its registration . . . inconsistent with the public interest'' under the CSA. *See, e.g.,* OSC, at 2 (alleging that Respondent ''repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that prescriptions were issued for a legitimate medical purpose, in violation of federal and state law''); *id.* at 8 (''It is my preliminary finding that [Respondent] repeatedly dispensed controlled substances without attempting to address or resolve clear red flags of drug abuse or diversion, which is inconsistent with the public interest.''). Therefore, although I agree with the Chief ALJ that the drafting could be improved, I

Continued

Respondent pharmacy violated federal and state law relating to controlled substances and dispensed prescriptions in such a way that violated its corresponding responsibility to ensure that controlled substances are dispensed only upon an effective prescription by failing to recognize and resolve red flags of diversion prior to dispensing. *See* 21 CFR 1306.04(a). Specifically, the Government alleges that the Respondent violated laws applicable to the dispensing of controlled substances by dispensing multiple controlled substances to the Ten Patients in the face of unresolved red flags indicating possible or even likely diversion. ALJ Ex. 1. The exact allegations charge that the Respondent ignored red flags based on: (1) High-risk combinations of controlled medications; (2) dosage anomalies; (3) cash payments; and (4) long distances between customers, prescribers, and the registrant pharmacy.

The evidence of record demonstrates that on numerous occasions the Respondent pharmacy filled prescriptions in the face of unresolved high-risk combination red flags and dosage-anomaly red flags (*i.e.,* illogical dosing combinations of long-acting and short-acting opioids, and therapeutic duplication). Gov't Exs. 6–14, 22, 23, 25–27, 29; Tr. 215–16, 218–21; Stip. 33 (Patient JW); Tr. 268–69, 274–76, 281–83; Stip. 19 (Patient EA); Tr. 287–91, 294–97; Stip. 21 (Patient SD); Tr. 302–05; Stip. 23 (Patient LH); Tr. 309–12, 315–16; Stip. 25 (Patient DH); Tr. 321–26; Stip. 27 (Patient DK); Tr. 330–38; Stip. 29 (Patient JM); Tr. 339–41; Stip. 31 (Patient ST); Tr. 243–45; Stip. 35 (Patient CW). Dr. Schossow persuasively testified that these red flags require documented resolution in order for the Respondent pharmacy to comply with its corresponding responsibility.[124] Tr. 204, 213–14, 216, 284–855, 318, 336–37. However, such adequate documentation was not present here. Tr. 431; Gov't Exs. 6–15, 22–29, 32; Tr. 240–41, 424–25 (Patient JW); Tr. 286, 371–75 (Patient EA); Tr. 295–300, 375–78 (Patient SD); Tr. 308, 378–80, 384 (Patient LH); Tr. 319, 321, 385–88, 397–98, 408–09 (Patient DH); Tr. 329–30, 409–13 (Patient DK); Tr. 338–39, 413–16, 419–20 (Patient JM); Tr. 342–43, 420–23 (Patient ST); Tr. 346–47, 425–30 (Patient CW). The Respondent's countering argument that the relevant standard of care in Florida does not require documentation of the resolution of red flags is unsupported by the applicable statutes and unpersuasive on this record.[*J] In specifically addressing high-risk combinations of controlled substances and controlled substance prescriptions with dosage anomalies, the Respondent's owner calmly and repeatedly explained that such occurrences did not raise any concern in his mind because such types of prescriptions are ''common.'' Tr. 1018, 1025, 1056, 1087, 1112–13, 1131, 1146–47. The owner was firm in his belief that every prescription at issue was dispensed properly and that his documentation was adequate. Tr. 1224.

The evidence of record demonstrates that the Respondent has neglected its corresponding responsibility imposed by the CSA and the Florida Administrative Code. *See* 21 CFR 1306.04(a) (establishing corresponding responsibility under the Controlled Substances Act); *Liddy's Pharmacy,* 76 FR 48,895 (affirming that only lawful prescriptions may be dispensed); Fla. Admin. Code Ann. r. 64B16–27.831 (establishing corresponding responsibility under Florida state law). The Respondent, through its PIC/owner, was derelict in executing its corresponding responsibility by dispensing in the face of an unresolved reason to believe that these prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice. *Cf. Med. Shoppe-Jonesborough,* 73 FR 381 (requiring a pharmacist to refuse to fill such prescriptions); *Medic-Aid Pharmacy,* 55 FR 30,044. By dispensing these prescriptions despite knowing that they were potentially dangerous and failing to investigate further, the Respondent pharmacy failed to follow its legal responsibilities. *See Sun & Lake Pharmacy,* 76 FR 24,530 (stating that a pharmacist may not ''close his eyes and thereby avoid [actual] knowledge'' of possible abuse or diversion) (quoting *Bertolino,* 55 FR 4730).

[Omitted for clarity. The record evidence establishes that it was outside the usual course of professional practice for Respondent to dispense] the prescriptions detailed in the Government's evidence and agreed stipulations without resolving the red flags presented and documenting that resolution.[125] The red flags detailed above required the Respondent and its owner/PIC to question these prescriptions, and they did not. *See Bertolino,* 55 FR 4730 (requiring pharmacists to question prescriptions that present red flags for abuse or diversion). [Omitted for clarity.]

The Government has presented uncontroverted evidence that the Respondent pharmacy dispensed multiple controlled substances in the face of multiple red flags of potential diversion.

Accordingly, OSC/ISO Allegations 6, 7.a, 7.b, 7.c, 7.e, 7.f, and 7.g (pertaining to high-risk combinations) are *sustained.* For the allegation pertaining to Patient SD,[126] the record contains insufficient quantitative evidence to support the amount of alprazolam specified for the alleged amount of dispensing events.[127] Accordingly, OSC/ISO Allegation 7.d is *sustained in part* to the extent that the charge alleges ''a quantity of alprazolam,'' while the remaining alleged dosages/amounts within OSC/ISO Allegation 7.d are *sustained* as charged.

The record contains sufficient quantitative evidence to preponderantly sustain the ratio dosage anomaly (illogical dosing combinations of long-acting and short-acting opioids) allegations for Patients JM,[128] ST,[129] DH,[130] and EA [131] as charged. Accordingly, OSC/ISO Allegations 10.a, 10.b, 10.c, and 10.f are *sustained.* [Omitted.] [*K 132 133 134]

The Government alleges that on multiple occasions where the Respondent dispensed multiple

also agree with him that Respondent was adequately noticed of the allegations against it in this case.]

[124] Additionally, the Agency has consistently sustained allegations that centered around unresolved high-risk combination red flags. *See, e.g., Suntree Pharmacy,* 85 FR 73,770; *Pharmacy Doctors Enters.,* 83 FR 10,876, 10,898 (2018); *E. Main St. Pharmacy,* 75 FR 66,165.

[*J] As explained above, *see supra* ns. *E, *I, my Decision does not rely on any interpretation of Florida law.

[125] As discussed elsewhere in this RD, the allegations centered on distance and cash red flags cannot be sustained based on the underlying rationale supplied by the Government's expert.

[126] ALJ Ex. 1 ¶ 7.d.

[127] *See Gregg & Son Distribs.,* 74 FR 17517, 17517 n.1 (2009) (clarifying that ''it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding'').

[128] ALJ Ex. 1 ¶ 10.a.

[129] ALJ Ex. 1 ¶ 10.b.

[130] ALJ Ex. 1 ¶ 10.c.

[131] ALJ Ex. 1 ¶ 10.f.

[*K] The Chief ALJ did not sustain the Government's improper dosing allegations related to Patients SD and LH. RD, at 78–79. The Government took Exception to this finding. Gov't Exceptions, at 5–7. I find that it is unnecessary for me to reach this issue because there is substantial other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest.

[132] ALJ Ex. 1 ¶ 10.d.

[133] ALJ Ex. 1 ¶ 10.e.

[134] *See Gregg & Son Distributors,* 74 FR 17,517 n.1 (noting that ''it is the Government's obligation as part of its burden of proof . . . to sift through the records and highlight that information which is probative of the issues in the proceeding'').

benzodiazepines (therapeutic duplication) to Patient JM, it failed to address or resolve this red flag in a way that would have been required to stay within the standard of care. Dr. Schossow's expert opinion has been deemed persuasive on this issue. Accordingly, OSC/ISO Allegation 12 is *sustained*.

Although Dr. Schossow's expert opinion has been held generally reliable, her theory regarding the basis for the cash red flag (*to wit,* that [Respondent failed to adequately resolve the cash red flag], even where lack of insurance was specifically noted by the pharmacy staff) was too logically challenged to serve as a basis for sanction. Certainly the Agency has consistently sustained supported allegations that centered around unresolved cash red flags in the past. *See, e.g., Suntree Pharmacy,* 85 FR 73770; *Pharmacy Doctors Enters.,* 83 FR 10,891; *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–13 (2014); *Holiday CVS,* 77 FR 62,317–22. [Omitted for clarity.] As discussed elsewhere in this recommended decision, the red flag resolution proposed by the Government's expert, *to wit,* that a dispenser-registrant is required in all cases to contact a prescriber-registrant to ascertain whether the customer-patient had prescription drug coverage (a subject within the exclusive purview of the pharmacy), does not further the goal of minimizing the risk of diversion. [Omitted.] *[L]

Further, it is beyond argument that there has been a long uncontradicted history of the Agency sustaining allegations relating to unresolved long-distance red flags. *See, e.g., Heavenly Care Pharmacy,* 85 FR 53,417; *Suntree Pharmacy,* 85 FR 73,770; *Pharmacy Doctors Enters.,* 83 FR 10,885; *Hills Pharmacy,* 81 FR 49,839; *Holiday CVS,* 77 FR 62,317–22; *E. Main St. Pharmacy,* 75 FR 66,163–65. The basis of that history is rooted in expert testimony explaining the common-sense proposition that traveling a great distance to fill a prescription that could have been dispensed around the block from the customer-patient raises a reasonable suspicion that the customer-patient may have chosen the remotely-located pharmacy for an improper purpose (*e.g.,* to escape scrutiny from local, vigilant pharmacists, or to travel to a pharmacy believed to be less vigilant in its responsibilities). *See, e.g., Holiday CVS,* 77 FR 62,334. Under those circumstances, experts have testified that it is logical and required to explore and resolve the possibility that either the patient-customer is seeking to mask his/her diversion, or the pharmacy has been identified as an easy mark for improperly-authorized prescriptions. [Omitted for brevity.]

This case presents a somewhat divergent issue. As discussed, *supra,* there is no genuine question that the distances between the customer-patient, the correlating prescriber, and the Respondent pharmacy are sufficiently lengthy as to objectively raise a red flag requiring pre-dispensing analysis and documentation. The fly in the ointment here is the primary rationale presented by Dr. Schossow as underlying the red flag. According to the Government's expert, a remarkable travel distance raises a concern, not founded in concerns related to drug diversion, but rather because a customer-patient filling prescriptions for opioids and benzodiazepines presents ''the risk for getting into a motor vehicle accident, [and] fractures, even death, [ ] could potentially occur.'' Tr. 232 [However, the witness testified] that she had no information regarding whether any of the customers in question drove to the Respondent pharmacy. Tr. 545. In addressing a distance red flag related to one of the customer-patients, Dr. Schossow supplied the following opinion about why the red flag stood unresolved:

> [I]f you're specifically talking about the red flag of distance, that would be asking the patient if he is actually driving a motor vehicle these distances while he's on these medications, back and forth, this long distance. And that was not addressed in this [pharmacy] note.

Tr. 380. Stated differently, if the Respondent had documented a representation by the customer-patient that someone drove him to the pharmacy the dispensing event would have met Dr. Schossow's standard. Even when closely pressed on the issue, Dr. Schossow held her ground, explaining that to resolve a distance red flag, when encountered, would require no more than the pharmacist to procure a representation from the customer-patient that someone else was doing the driving to the pharmacy.[135] Tr. 237–39.

By the testimony of the Government's expert, the long-distance red flags in this case were not founded in controlled-substance diversion (which is the focus of this proceeding and which circumscribe the hardline limits of this Agency's jurisdiction); instead, the Government expert's explanation of long-distance red flags related to general patient safety concerns. Dr. Schossow's view paints safety with a broader brush than DEA's statutory authority allows.[136] Safer roads do not translate into lack of drug diversion, and more dangerous road conditions do not likewise translate into establishing the applicable dispensing standard for a DEA pharmacy registrant. This Agency is charged with administering the Controlled Substances Act, with no mandate to supervise highway and traffic safety. Accordingly, OSC/ISO Allegations 8.a, 8.b, 8.c, 8.d, 8.e,[137] and 8.f are *not sustained*.

The Government further alleges that the Respondent filled prescriptions for alprazolam to Patients JW, EA, and SD in amounts that presented a red flag (because the dosages were pharmacologically illogical) without attempting to address the red flag. However, the Government presented no evidence that this occurred (nor did it address the issue in its post-hearing brief);[138] thus, it appears the Government has abandoned these allegations, *see Pursley,* 85 FR 80,181–82, 80,185. Accordingly, OSC/ISO Allegation 11 is *not sustained*.

OSC/ISO Allegation 1 is *sustained* based on the evidence[139] and stipulations[140] of record.

*[L] Omitted. The Government has taken Exception to the RD's finding that allegation 13 was not sustained. Gov't Exceptions, at 1–5. I agree with the Chief ALJ that Dr. Schossow's method for resolving the red flag was logistically problematic. Still, I find that Dr. Schossow credibly testified that cash payments are a red flag that requires documented resolution. Ultimately, I find that it is unnecessary for me to reach this issue because there is substantial other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest.

[135] The witness also allowed that the existence and resolution of a distance red flag could be different if the pharmacy and the prescriber were collocated in the same building. Tr. 238. But even where the dispenser and prescriber were located miles away, Dr. Schossow kept her focus on whether the patient-customer was doing the driving. Tr. 239.

[136] *See Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (the setting of medical standards is a function of the police powers of a state, whereas DEA's authority under the CSA is limited to barring illicit drug dealing and trafficking as traditionally understood).

[137] While OSC/ISO Allegation 8.e charges the Respondent with dispensing controlled substances to Patient EA in the face of long-distance red flags, the Government presented no evidence on this issue during the hearing and did not address the issue in its post-hearing brief. Therefore, the Government has apparently abandoned OSC/ISO Allegation 8.e. *See George Pursley, M.D.,* 85 FR 80,162, 80,181–82, 80,185 (2020) (finding the Government abandoned allegation by not addressing it within its post-hearing brief).

[138] Again, *see Gregg & Son Distributors,* 74 FR 17,517 n.1 (clarifying that ''it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding'').

[139] Gov't Ex. 1.

[140] Stips. 1, 2.

[Accordingly, I find that Respondent has operated outside the usual course of professional practice (in violation of 21 CFR 1306.06 and Fla. Admin. Code Ann. r. 64B16–27.831 and in violation of its corresponding responsibility (in violation of 21 CFR 1306.04(a) and Fla. Admin. Code Ann. r. 64B16–27.831). I further find that the Government has made a *prima facie* case that the Respondent has committed acts which render its registration inconsistent with the public interest.] *[M] On consideration of the whole of the record, it is clear that Public Interest Factors Two and Four militate strongly in favor of the imposition of a registration sanction in this case.

[Sanction]

The evidence of record preponderantly establishes that the Respondent has committed acts which render its continued registration inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4). Since the Government has met its burden [141] in demonstrating that the revocation it seeks is authorized, to avoid sanction, it becomes incumbent upon the Respondent to demonstrate that given the totality of the facts and circumstances revocation is not warranted. *See Med. Shoppe-Jonesborough,* 73 FR 387. That is, upon the preponderant establishment of the Government's *prima facie* case, the burden now shifts to the Respondent to show why it should continue to be entrusted with a DEA registration. *See Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45,667, 45,689 (2020); *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018).

Although by no means the only requirement, in order to rebut the Government's *prima facie* case, the Respondent must demonstrate both an unequivocal acceptance of responsibility and also a demonstrable plan of action to avoid similar conduct in the future. *See Hassman,* 75 FR 8236. While those two elements are key, the focus is, and must always be, rooted in a determination as to whether the Agency can have confidence that the Respondent can continue to be entrusted with the weighty and dangerous responsibilities of a registrant. *Cf. Khan-Jaffery, M.D.,* 85 FR 45,689; *Smith, M.D.,* 83 FR 18,910. While analytical frameworks applied to prior Agency actions provide useful guidance and helpful structure, such tools cannot distract the Agency from its critical mission to keep the public safe by only issuing and maintaining CORs in cases where the public is adequately protected. The central issue is whether, based on the evidence of record, including the Respondent's established misdeeds, the Agency can trust the Respondent with the authority to handle dangerous controlled substances. The Agency has provided the following framework for its analysis in this regard:

> The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations. A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction; as is whether the registrant's acceptance of responsibility is unequivocal.

Heavenly Care Pharmacy, 85 FR 53,420 (internal citations omitted).

Agency precedent is clear that a respondent must ''unequivocally admit fault'' as opposed to a ''generalized acceptance of responsibility.'' *The Medicine Shoppe,* 79 FR 59,510; *see also Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017). To satisfy this burden, the respondent must show ''true remorse'' or an ''acknowledgment of wrongdoing.'' *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011). The Agency has made it clear that unequivocal acceptance of responsibility is paramount for avoiding a sanction. *Dougherty,* 76 FR 16,834 (citing *Krishna-Iyer,* 74 FR 464). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Jones Total Health Care Pharmacy, LLC* v. *DEA,* 881 F.3d 823, 830–31 (11th Cir. 2018); *MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011); *Hoxie,* 419 F.3d at 483.

For both prongs (acceptance of responsibility and remedial steps), the Respondent [did not present any evidence]. Arguably, as discussed, *supra,* at some point (outside the timeframe of the allegations) the evidence of record showed that the Respondent did appear to commence at least some documentation of some conversations with prescribers and patients.[142] However, as discussed, *supra,* the Respondent's owner made his view unflinchingly clear that the documentation level required to dispense within the standard applicable in the State of Florida is ''absolutely absurd.'' Tr. 1096. The Respondent's owner, in the clearest terms possible, like the expert he called to meet the Government's evidence, has demonstrated active hostility to applying this standard in the past, in the present, and in the future, as well as his amenability to Agency oversight. Thus, the Respondent accepts responsibility on no level, much less unequivocally. A change in this attitude is unlikely. The view of the Respondent's owner/PIC is that no misconduct or deficits occurred, and to the extent that the Agency and its expert thinks otherwise, it is mistaken.

While the transgressions alleged and proved here are certainly serious, it is arguable that an acceptance of responsibility, coupled with a thoughtful plan of remedial action on the part of the Respondent pharmacy, would have had the potential for a creditable case for lenity. The errant dispensing events that were sustained involved areas of prescribing and dispensing that may well have been amenable to a convincing case that the Respondent's owner re-educated himself and now understood that follow-up and documentation are required to bring his pharmacy within the applicable standard. The Respondent pharmacy was clearly operating below an acceptable and safe standard, but it could not fairly be said that the pharmacy was a pill mill. On these facts, an unequivocal acceptance of responsibility and meaningful remedial steps could conceivably have supported a more moderate sanction. To the extent that the Respondent's owner had expressed some level of contrition coupled with an expression of some understanding of why his pharmacy was operating below the applicable standard, it could have achieved much in empowering the Agency to exercise some measure of lenity as a matter of discretion. But in view of the present record, considering what could have been on a different record is of minimal utility.

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*[M] For purposes of the imminent danger inquiry, my findings lead to the conclusion that Respondent has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial evidence that Respondent dispensed controlled substance prescriptions outside the usual course of the professional practice established ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registration.'' *Id.* There was ample evidence introduced to establish that Respondent, without first resolving red flags, repeatedly dispensed combinations of medications that posed serious risks to patients. Thus, I find that at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger.

[141] *See* 21 CFR 1301.44(e).

[142] This is only an evidentiary observation, not a point propounded by the Respondent regarding remedial steps.

The Agency has frequently required unambiguous acceptance of responsibility and a remedial action plan as an essential component to avoid a sanction,[143] and in this case it is clear that the Respondent's owner, acknowledging no deficiencies, has no plan to conform his conduct whatsoever. In his view, he and his pharmacy did nothing wrong and would presumably make all the same choices if faced with the same facts tomorrow. The Agency is thus faced with a choice of imposing a registration sanction or imposing none and therein creating a virtual guarantee that it will be instituting new proceedings, charging the same conduct, on the day it issues its final order. On this point there is little room for logical, dispassionate dissent. Thus, in the face of a *prima facie* case, without the Respondent meeting the evidence with an acceptance of responsibility and proposing remedial measures geared toward avoiding future transgressions, the record supports the imposition of a sanction.

Further, inasmuch as the evidence of record fails to demonstrate an unequivocal acceptance of responsibility, the issue of remedial steps becomes irrelevant. The Agency has consistently held that for either prong (acceptance of responsibility and remedial steps) to be considered in sanction amelioration, both prongs must have been established. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019); *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care,* 81 FR 79,188, 79,202–03 (2016); *Hassman,* 75 FR 8236. If one prong is absent, the other becomes irrelevant. Both or neither has been the rule for many years. The view of the Respondent's owner that nothing is wrong with his pharmacy has virtually precluded him from establishing remedial steps of any kind. As noted, *supra,* there was some indication of a sporadic, mildly increased level of documentation beyond the temporal range of the allegations, but these were not even proffered as remedial steps. Thus, in view of the *prima facie* case established by the Government's evidence, without the Respondent meeting the evidence with a convincing, unequivocal acceptance of responsibility and proposing thoughtful, concrete remedial measures geared toward avoiding future transgressions, the record supports the imposition of a sanction. That a sanction is supported does not end the inquiry, however.

In determining whether and to what extent imposing a sanction is appropriate, consideration must also be given to the Agency's interest in both specific and general deterrence and the egregiousness of the offenses established by the Government's evidence. *Ruben,* 78 FR 38,364, 38,385. The issue of the egregiousness of the offense favors revocation. The Respondent dispensed many controlled substances for over a year without any regard for its obligations to identify blatant red flags of potential diversion. There was no indication during the hearing that the Respondent's owner did not understand his true obligations, only that he [resented those obligations.] The Respondent pharmacy [repeatedly dispensed controlled substances without appreciating that] further steps were required to resolve and document indications of potential diversion.

Considerations of specific and general deterrence in this case militate in favor of revocation. Through the testimony of its owner, [it was clear that the Respondent did not feel that it had acted improperly, did not have a fulsome understanding of the requirements for operating in the usual course of professional practice, and did not believe that any actions the Respondent might take to curtail diversion would matter to DEA]. The Respondent's owner and its expert witness [apparently believe] that DEA has no proper oversight role in the operation of the Respondent pharmacy and pharmacy practice in general.[144] The Respondent's owner [testified] that even the isolated instances of an increased level of documentation were effected, not in the interests of compliance with the applicable state standards, but to placate DEA. Tr. 1218–22, 1226–27. The Respondent's owner is not amenable to supervision by regulatory authorities, including DEA. He believes he is and has been correct, and it can be confidently assumed that the absence of a registration sanction will result in the continuation of business as usual at his pharmacy. Thus, the interests of specific deterrence, even standing alone, motivate powerfully in favor of the revocation of the Respondent's COR.

The interests of general deterrence compel a like result. As the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben,* 78 FR 38,385. Where the record demonstrates that the Government has borne its burden and established that the Respondent has dispensed high numbers of controlled substances below the standard for over a year with no correction and no remorse, the unmistakable message to the regulated community would be that such conduct can be tried once (or more than once) with little or no consequence. Thus, on this record, the interests of general deterrence support the revocation sought by the Government.

Another factor that weighs significantly in favor of the revocation sanction sought by the Government is the profound lack of candor demonstrated by the Respondent's owner during his testimony and his actions during the investigation. In making the public interest determination, this Agency places great weight on a respondent's candor both during an investigation and during a subsequent proceeding. *Fred Samimi, M.D.,* 79 FR 18,698, 18,713 (2014); *Robert F. Hunt, D.O.,* 75 FR 49,995, 50,004 (2010). As discussed at length, *supra,* during the investigation in this matter, the Respondent declined to forward a large swath of material specifically subpoenaed by DEA investigators, and during the hearing there were marked and profound adverse issues regarding the credibility of the owner's testimony. Hence, the issue of candor to the Agency, and candor to the tribunal, undermine the confidence that the Agency can have in the Respondent's continuation as a DEA registrant.

Accordingly, it is respectfully recommended that the Respondent's DEA COR should be *revoked,* and any pending applications for renewal should be *denied*.

Dated: April 7, 2021
John H. Mulrooney, II
Chief Administrative Law Judge

The Respondent's Exceptions

On December 15, 2020, Respondent filed its exceptions to the Recommended Decision. DEA regulations require that Exceptions ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. For the most part, Respondent's Exceptions not only fail to comply with this regulatory requirement, but they also lack evidentiary support in the Administrative Record. Several of

[143] *Hassman,* 75 FR 8236. [Edited the footnoted sentence for clarity.]

[144] As discussed, *supra,* the Respondent's owner received multiple unsubtle entreaties from the tribunal to distance himself from his expert's hostility to the exercise of regulatory authority by DEA, all of which were soundly declined. Tr. 1222–24.

Respondent's Exceptions also reflect a misunderstanding of the CSA and its implementing regulations. Additionally, some of Respondent's Exceptions repeat arguments that were already raised in Respondent's Posthearing Brief, or in prehearing or posthearing filings, and have been adequately addressed in the adopted Recommended Decision or in the Chief ALJ's orders. Therefore, I reject Respondent's Exceptions and adopt the Recommended Decision of the Chief ALJ as amended above.

Exception A

Respondent argues in its first Exception that the Government failed to demonstrate that Respondent's prescribing ''posed imminent harm to the public,'' and that the Chief ALJ ''departed from established standard'' by recommending that Respondent's registration be revoked without any evidence of public harm. Resp Exceptions, at 2–3. However, Respondent does not cite legal authority for the proposition that I must find evidence of diversion or harm before I may suspend or revoke a registration. Agency Decisions have found that DEA has the authority to revoke a DEA registration in the absence of evidence of diversion if the registrant's ''practices . . . create a substantial risk of diversion'' or even the ''opportunity for diversion.'' *See, e.g., Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,905 n.32 (2018) (citing *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,974 n.35 (2010). Further, DEA has held that ''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and could justify revocation or denial.'' *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,601).

As discussed in more detail above, DEA is authorized to revoke a registration upon a finding that the registrant's registration is ''inconsistent with the public interest,'' based on a consideration of five enumerated factors, including the registrant's ''experience dispensing . . . controlled substances'' and the registrant's ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(f). In this case, I find that the Government has met its burden of proving that Respondent's registration is inconsistent with the public interest by presenting evidence that Respondent repeatedly filled prescriptions that presented obvious and well-established red flags of drug abuse and diversion, in violation of federal and state law. Agency Decisions have consistently held that the repeated filling of prescriptions in violation of federal and state law constitutes acts that are inconsistent with the public interest, and establish grounds for DEA to revoke a registration. *See, e.g., Suntree Pharmacy,* 85 FR 73,776.

Moreover, Respondent's Exception conflates the legal standard for issuing an immediate suspension order under 21 U.S.C. 824(d) with the legal standard for revoking a registration under 21 U.S.C. 823(f). Before issuing an ISO, the Government must demonstrate that the registrant has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant,'' and that those failures have created a ''substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registration.'' 21 U.S.C. 824(d) (emphasis added).*[N]As discussed in more detail above, *see supra* n.*M, I find that at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger.

Exception B

Respondent next takes exception to the Chief ALJ's characterization of Dr. Schossow's expert testimony. Resp Exceptions, at 4–6. Respondent argues that Dr. Schossow's testimony should not be given any weight for several reasons. First, Respondent argues that Dr. Schossow cannot be trusted because she initially testified that she had sat on the Florida board of pharmacy in the 1990s, and later confirmed that she had not. Second, Respondent argues that Dr. Schossow's opinions were entitled to little weight because she did not speak to the physicians, pharmacists, and customers involved in Respondent's dispensing, and she had never been to Respondent pharmacy. Respondent identifies several additional concerns with Dr. Schossow's testimony, including that her opinions were illogical and based on speculation, that she did not identify any evidence that Respondent's customers were abusing controlled substances, and that she did not have adequate information to conclude whether there was imminent danger or public harm.

I agree with the Chief ALJ's assessment of Dr. Schossow's credibility,*[O] including his determination that Dr. Schossow's misstatement about the Florida board of pharmacy was not material. *See* ALJ Ex. 67 (Order Denying the Respondent's Motion to Disqualify Expert Witness). I also find that Dr. Schossow reviewed sufficient materials to provide relevant opinions on Respondent's compliance with the usual course of professional practice in Florida, and that her failure to speak to any of the involved pharmacists, physicians, or customers did not diminish the weight of her opinions. Dr. Schossow's opinions primarily focused on Respondent's failure to document a resolution of red flags of drug abuse and diversion. Respondent's failure to document was sufficient evidence that Respondent's dispensing was outside the usual course of professional practice, even without input from any of Respondent's pharmacists or customers, or the prescribing physicians.

Respondent's additional concerns about the allegedly illogical and inconsistent nature of Dr. Schossow's opinions are not adequately supported by citations to the record that would allow me to meaningfully respond. *See* 21 CFR 1316.66. As stated above, I agree with the Chief ALJ's credibility determinations and his analysis of Dr. Schossow's opinions. I find that the Chief ALJ thoroughly and neutrally analyzed Dr. Schossow's credibility and identified portions of her testimony that were illogical or internally inconsistent, and relied only on those portions that were logical and well-supported.

Finally, as stated above, Respondent does not cite legal authority for the proposition that I must find evidence of diversion or harm before I may suspend or revoke a registration. It is therefore irrelevant to my Decision whether the Government's expert believed that there was actual harm.

Exception C

Respondent next takes Exception to the Chief ALJ's questions to Respondent's representative, Dr.

*[N] In support of this argument, Respondent quotes from a West Virginia District Court order granting a pharmacy's motion to dissolve an immediate suspension order. The district court found that the Government had not adequately supported its imminent danger finding, because it had not ''demonstrat[ed] that actual or anticipated harm had occurred in patients.'' *Id.* (*citing Oakhill Hometown Pharmacy* v. *Uttam Dhillon,* 2:19–cv–00716, at 9). Respondent's reliance on this decision is misplaced, and it has no relevance to this proceeding. Respondent's legal course of action on this matter would have been to challenge the ISO in court. The subject of this proceeding is the revocation of Respondent's registration. I am finding in favor of revocation, and therefore, at the time that my order goes into effect, the immediate suspension will necessarily end.

*[O] It is well-settled that because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *Universal Camera Corp.,* 340 U.S. at 496, and that this Recommended Decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179.

Howard, about whether he agreed with certain testimony by Respondent's expert, Dr. Buffington. Resp Exceptions, at 6–8. Respondent believes that the Chief ALJ's questions to Dr. Howard misstated Dr. Buffington's opinions and that they put Dr. Howard in the uncomfortable position of deciding whether to agree with Dr. Buffington's opinions. *Id.*

As discussed in more detail above, ALJs have authority to regulate the administrative hearing, which includes asking clarifying questions of counsel and witnesses and issuing evidentiary rulings. *See supra* n. *A (citing 5 U.S.C. 556(c)(5); 21 CFR 1316.52(e)). In this case, the Chief ALJ was questioning Dr. Howard for Respondent's benefit in an attempt to ascertain whether Respondent shared Dr. Buffington's criticisms of—and hostility towards—DEA as a regulator. Respondent's attitude towards DEA, and appreciation for the requirements for operating in the usual course of professional practice, are relevant to DEA's determination as to Respondent's likelihood of future compliance in determining whether a sanction is appropriate.*P I therefore find that the Chief ALJ properly exercised his discretionary authority to regulate the hearing and that Respondent's Exception is without merit.

Exception D

Respondent next argues that the Chief ALJ improperly excluded Respondent's Second Supplemental Prehearing Statement (hereinafter, Second SPS), which was filed approximately five months after the deadline set by the Prehearing Ruling. Resp Exceptions, at 8–9. Respondent's Second SPS was also not accompanied by a motion for good cause, which is a prerequisite for a late-filed prehearing statement.*Q The Government filed a Motion to Strike (*see* ALJ Ex. 34), and Respondent replied to that motion (*see* ALJ Ex. 35), arguing that there should be no prejudice to the Government from the late filing. The Chief ALJ determined that Respondent had not provided any rationale or good cause for its late filing.*R Order Denying Respondent's Motion, at n. 3. As previously mentioned, the Chief ALJ has authority to regulate the hearing, which includes the authority to exclude evidence. 21 CFR 1316.52(e). I therefore defer to his decision to exclude Respondent's Second SPS.

I also find that there was no prejudice to the Respondent from the Chief ALJ's denial of its Second SPS. The Second SPS did not notice any new witnesses or testimony; it simply noticed Respondent's intention to amend ten of Respondent's previously-disclosed exhibits. Respondent stated that the amended exhibits contained additional ''[drug utilization review] data.'' *See* Second SPS, at 2. Although the Chief ALJ did not permit Respondent to amend these exhibits before the hearing, he allowed Respondent to attempt to authenticate the amended exhibits at the hearing ''to afford the Respondent the maximum level of due process.'' RD, at n. 106 (citing Tr. 642–60). Thus, the Chief ALJ essentially reversed his decision to deny the Second SPS by permitting the Respondent to offer the amended exhibits into evidence.

In the RD, the Chief ALJ referred to the amended exhibits as the outside-of-record (OOR) documents. *See* RD, at n. 106. Respondent attempted to admit one of the OOR documents at the hearing, but the Chief ALJ declined to admit it because there were ''fundamental issues regarding inadequate foundation and reliability.'' *Id.* Respondent did not offer the remaining OOR documents into the record after the first document was denied. *Id.* However, Respondent's counsel repeatedly refreshed Dr. Howard's recollection with the OOR documents, which gave Dr. Howard the opportunity to testify about any notations in the OOR documents that evidenced attempts by Respondent to conduct a drug utilization review. *See supra* Respondent's Case, Summary of Dr. Howard's Testimony.*S I find that Respondent was given ample opportunity at the hearing to provide the tribunal with all reliable evidence of its attempts to exercise due diligence efforts.

Respondent further argues that the Chief ALJ's decision to exclude the Second SPS was arbitrary in light of his decision to take official notice of an FDA black box warning that cautions against concurrent prescribing of opioids and benzodiazepines, which was not identified in the Government's prehearing filings. Resp Exceptions, at 8–9. However, on this issue, Respondent's counsel did not object to the official notice and agreed that there was no serious notice issue. *See* ALJ Ex. 39. I defer to the Chief ALJ's decision to take official notice of this document, which was an exercise of his authority to regulate the hearing. As stated above, courts have uniformly held that judicial rulings issued during the course of litigation rarely constitute evidence of cognizable bias. Order Denying the Respondent's Recusal Motions (citing *Liteky* v. *United States,* 510 U.S. 540, 555 (1994), *Hamm* v. *Members of Bd. of Regents,* 708 F.2d 647, 651 (11th Cir. 1983), *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,958–59 (2010)). Further, the contents of this document should not have been a surprise to Respondent, because this document is publicly available and widely known, and the Government had notified Respondent that its expert would testify about the dangers of prescribing opioids and benzodiazepines concurrently. *See e.g.,* ALJ Ex. 4 (Gov't Prehearing), at 20–21; *see also* OSC/ISO, at 3.

Exception E

Finally, Respondent argues that the Chief ALJ erred in finding that Dr. Howard's hearing testimony suffered from diminished credibility. Resp Exceptions, at 9–11. In support of this argument, Respondent cites to only one page of the transcript, where the Chief ALJ faulted Dr. Howard for failing to remember testimony from the day before. Resp Exceptions, at 9 (citing Tr. 53). Respondent's Exception fails because it does not ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. Respondent's Exception also

*P *See, e.g.,* Jayam Krishna-Iyer, 74 FR 459, 463 (2009) (stating that ''where a registrant has committed acts inconsistent with the public interest, the registrant must . . . demonstrate that [it] will not engage in future misconduct'') (quoting Medicine Shoppe, 73 FR 364, 387 (2008)); *see also Lisa Hamilton, N.P.,* 85 FR 71,465, 71,473 (2019) (observing, in determining that revocation was the appropriate remedy, that the respondent had ''demonstrated a general disdain for the charges against her and the situation in which she had found herself'').

*Q ALJ Ex. 36, at 2 (Order Denying the Respondent's Motion to File a Second Supplemental Prehearing Statement) (citing Prehearing Ruling, at 2; 21 CFR 1316.55 (stating that a prehearing ruling issued in an administrative enforcement action ''shall control the subsequent course of the hearing unless modified by a subsequent ruling'')).

*R Respondent disagrees with the Chief ALJ's determination that it did not provide good cause for the late filing. Resp Exceptions, at 8. Respondent argues that ''[t]here was good cause provided with the background setting of the pandemic that had caused the case to stay on hold for nearly a year,'' and ''[c]ounsel stated that there was no prejudice to the Government and that the pandemic and his recent notice of appearance in the case were the basis of the untimely Prehearing Statement.'' *Id.* However, the Chief ALJ was aware of the pandemic's impact on the litigation when he decided to exclude Respondent's Second SPS, and he determined that Respondent had not provided good cause. Order Denying Respondent's Motion, at 2–3.

*S As the RD observes, Respondent could have sought to introduce the OOR documents into the record as past recollection recorded, but declined to do so. *See* RD, at 107 (citing Fed. R. Evid. 803(5)).

fails because, after reviewing the entire record, I find that the Chief ALJ thoroughly and accurately analyzed Dr. Howard's credibility and his testimony, and I agree with his credibility findings.

I therefore reject Respondent's Exceptions and issue the following Order.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FA2125640 issued to AARRIC, Inc. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of AARRIC, Inc. for additional registration in Florida. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that any controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–00955 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until February 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act as Amended.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0001. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes STOP formula grantees (50 states, the District of Columbia and five territories (Guam, Puerto Rico, American Samoa, Virgin Islands, Northern Mariana Islands). The STOP Violence Against Women Formula Grant Program was authorized through the Violence Against Women Act of 1994 and reauthorized and amended in 2000, 2005, and 2013. The purpose of the STOP Formula Grant Program is to promote a coordinated, multi-disciplinary approach to improving the criminal justice system's response to violence against women. It envisions a partnership among law enforcement, prosecution, courts, and victim advocacy organizations to enhance victim safety and hold offenders accountable for their crimes of violence against women. The Department of Justice's Office on Violence Against Women (OVW) administers the STOP Formula Grant Program funds which must be distributed by STOP state administrators according to statutory formula (as amended in 2000, 2005 and 2013).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 56 respondents (state administrators from the STOP Formula Grant Program) less than one hour to complete a Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act, as Amended.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the Certification is less than 56 hours.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: January 13, 2022.

Melody Braswell,

Department Clearance Officer, PRA U.S. Department of Justice.

[FR Doc. 2022–00960 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0080]

Agency Information Collection Activities: Extension of a Currently Approved Collection: Annuity Broker Declaration Form

ACTION: 60-Day notice of information collection under review.

The Department of Justice (DOJ), Civil Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days until March 21, 2022.

If you have questions concerning the collection, please contact James G.

Touhey, Jr., Director, Torts Branch, Civil Division, U.S. Department of Justice, P.O. Box 888, Benjamin Franklin Station, Washington, DC 20044, Telephone: (202) 616–4400. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—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;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Annuity Broker Qualification Declaration Form.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* U.S. Department of Justice, Civil Division.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals. Abstract: This declaration is to be submitted annually to determine whether a broker meets the qualifications to be listed as an annuity broker pursuant to Section 111015(b) of Public Law 107–273.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 300 respondents will complete the form annually within approximately 1 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual burden hours to complete the certification form is 300 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: January 13, 2022.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2022–00951 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0009]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Revision of a Currently Approved Collection; Application To Register as an Importer of U.S. Munitions Import List (USMIL) Articles—ATF Form 4587(5330.4)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ) will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until February 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *The Title of the Form/Collection:* Application to Register as an Importer of U.S. Munitions Import List (USMIL) Articles.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 4587(5330.4).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individuals or households.

Abstract: The Application to Register as an Importer of U.S. Munitions Import List (USMIL) Articles—ATF Form 4587(5330.4) is used to register an individual or company as an importer of USMIL articles and facilitate the collection of registration fees.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 400 respondents will complete this form once annually, and it will take each respondent 30 minutes to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 200 hours, which is equal to 400 (total respondents) * 1 (# of response per respondent) * .5 (30 minutes or the time taken to prepare each response).

(7) *An Explanation of the Change in Estimates:* Due to more individuals registering to import defense articles and services, the total respondents, responses, and burden hours to this collection have increased from 300, 300, and 150 hours respectively in 2018, to 400, 400, and 200 hours currently.

If additional information is required contact: Melody Braswell, Department

Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–405A, Washington, DC 20530.

Dated: January 13, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–00950 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–FW–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0025]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection; Federal Coal Lease Request

AGENCY: Antitrust Division, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Antitrust Division (ATR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until February 18, 2022.

ADDRESSES: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jill Ptacek, Attorney, Antitrust Division, United States Department of Justice, 450 Fifth Street NW, Suite 8000, Washington, DC 20530 (phone: 202–307–6607).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Federal Coal Lease Reserves.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form numbers are ATR–139 and ATR–140. The applicable component within the Department of Justice is the Antitrust Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for profit. Other: None. The Department of Justice evaluates the competitive impact of issuances, transfers and exchanges of federal coal leases. These forms seek information regarding a prospective coal lessee's existing coal reserves. The Department uses this information to determine whether the issuance, transfer or exchange of the federal coal lease is consistent with the antitrust laws.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 10 respondents will complete each form, with each response taking approximately two hours.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 20 annual burden hours associated with this collection, in total.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: January 13, 2022.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2022–00953 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–12–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

TIME AND DATE: The Legal Services Corporation's (LSC) Board of Directors and its six committees will meet January 27–28, 2022. On Thursday, January 27, the first meeting will begin at 11 a.m. Eastern Standard Time (EST), with the next meeting commencing promptly upon adjournment of the immediately preceding meeting. On Friday, January 28, the first meeting will again begin at 12 p.m., EST, with the next meeting commencing promptly upon adjournment of the immediately preceding meeting.

PLACE:

Public Notice of Virtual Meeting.

LSC will conduct the January 27–28, 2022 meetings virtually via Zoom.

Public Observation: Unless otherwise noted herein, the Board and all committee meetings will be open to public observation. Members of the public who wish to participate remotely in the public proceedings may do so by following the directions provided below.

Directions for Open Sessions

Thursday, January 27, 2022

- To join the Zoom meeting by computer, please use this link.
- *https://lsc-gov.zoom.us/j/92803095997?pwd=dTdGSkZZZ21YREVwWURmZm1EU2FRUT09.*
  - Meeting ID: 928 0309 5997
  - Passcode: 12722
- To join the Zoom meeting with one tap from your mobile phone, please click dial:
  - +16468769923,,92803095997# US (New York)
  - +13017158592,,92803095997# US (Washington DC)
- To join the Zoom meeting by telephone, please dial one of the following numbers:
  - +1 301 715 8592 US (Washington DC)
  - +1 646 876 9923 US (New York)
  - +1 312 626 6799 US (Chicago)
  - +1 669 900 6833 US (San Jose)
  - +1 253 215 8782 US (Tacoma)
  - +1 346 248 7799 US (Houston)
  - +1 408 638 0968 US (San Jose)
  - *Meeting ID:* 928 0309 5997
  - *Passcode:* 12722
  - If calling from outside the U.S., find your local number here: *https://lsc-gov.zoom.us/u/acCVpRj1FD*

Friday, January 28, 2022

- To join the Zoom meeting by computer, please use this link.

- *https://lsc-gov.zoom.us/j/95951870668?pwd=bThoZ0pVL0M3Q3ZYR2x3SEovalJkQT09.*
  - Meeting ID: 959 5187 0668
  - Passcode: 12822
- To join the Zoom meeting with one tap from your mobile phone, please click dial:
  - +13126266799,,95951870668# US (Chicago)
  - +13017158592,,93655413488# US (Washington DC)
- To join the Zoom meeting by telephone, please dial one of the following numbers:
  - +1 301 715 8592 US (Washington DC)
  - +1 312 626 6799 US (Chicago)
  - +1 646 876 9923 US (New York)
  - +1 253 215 8782 US (Tacoma)
  - +1 346 248 7799 US (Houston)
  - +1 408 638 0968 US (San Jose)
  - +1 669 900 6833 US (San Jose)
  - *Meeting ID:* 959 5187 0668
  - *Passcode:* 12822
  - If calling from outside the U.S., find your local number here: *https://lsc-gov.zoom.us/u/acCVpRj1FD*

Once connected to Zoom, please immediately mute your computer or telephone. Members of the public are asked to keep their computers or telephones muted to eliminate background noise. To avoid disrupting the meetings, please refrain from placing the call on hold if doing so will trigger recorded music or other sound.

From time to time, the Board or Committee Chair may solicit comments from the public. To participate in the meeting during public comment, use the 'raise your hand' or 'chat' functions in Zoom and wait to be recognized by the Chair before stating your questions and/or comments.

STATUS: Open, except as noted below.

Institutional Advancement Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to receive a briefing on development activities and discuss prospective new Leaders Council and Emerging Leaders Council members.

Audit Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to discuss follow-up work by the Office of Compliance and Enforcement relating to open Office of Inspector General Investigations.

Finance Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to discuss LSC's banking services and investment policy.

Board of Directors—Open, except that, upon a vote of the Board of Directors, a portion of the meeting may be closed to the public for briefings by management and LSC's Inspector General, and to consider and act on the General Counsel's report on potential and pending litigation involving LSC and prospective Leaders Council and Emerging Leaders Council members.

Any portion of the closed session consisting solely of briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to such portion of the closed session.[1]

A verbatim written transcript will be made of the closed session of the Board, Audit, Finance, and Institutional Advancement Committee meetings. The transcript of any portions of the closed sessions falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6), (7), (9) and (10), will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

MEETING SCHEDULE

	Start time (all EST)
Thursday, January 27, 2022:	
1. Governance and Performance Review Committee Meeting	11 a.m.
2. Operations and Regulations Committee Meeting.	
3. Finance Committee Meeting.	
4. Audit Committee Meeting.	
Friday, January 28, 2022:	
1. Institutional Advancement (IAC) Committee Meeting	12 p.m.
2. Institutional Advancement (IAC) Communications Subcommittee Meeting.	
3. Delivery of Legal Services Committee Meeting.	
4. Open Board Meeting.	
5. Closed Board Meeting.	

Thursday, January 27, 2022

Governance and Performance Review Committee

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Committee's Open Session Meeting on October 25, 2021
3. Briefing on Legal Aid and the Executive Branch
   a. White House and U.S. Department of Justice meeting of Legal Aid Interagency Roundtable
   b. White House, U.S. Department of Justice and U.S. Department of Treasury listening sessions on eviction
   - Carol Bergman, Vice President for Government Relations & Public Affairs
   - Ron Flagg, President
4. Report on Annual Board and Committee Evaluations
   - Carol Bergman, Vice President for Government Relations & Public Affairs
5. Report on the Governance & Performance Review Committee Evaluation for 2021 and Goals for 2022
   - Carol Bergman, Vice President for Government Relations & Public Affairs
6. Discussion of LSC President's 2021 Evaluation
   - Ron Flagg, President
7. Discussion of Inspector General's 2021 Activities
   - Jeff Schanz, Inspector General
8. Public Comment
9. Consider and Act on Other Business
10. Consider and Act on Adjournment of Meeting

[1] 5 U.S.C. 552b(a)(2) and (b). See also 45 CFR 1622.2 & 1622.3.

Operations and Regulations Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Committee's Open Session Meeting on October 25, 2021
3. Discussion of the Committee's Evaluation for 2021 and the Committee's Goals for 2022
4. Discussion of Management's Report on Implementation of LSC's Strategic Plan for 2021–2024
   - Ron Flagg, President
5. Update on Retrospective Review Process
   - Stefanie Davis, Senior Assistant General Counsel and Ethics Officer
6. Public Comment
7. Consider and Act on Other Business
8. Consider and Act on Adjournment of Meeting

Finance Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of the Minutes of the Committee's Open Session Meeting on October 26, 2021
3. Discussion of the Committee's Evaluation for 2021 and the Committee's Goals for 2022
4. Discussion of LSC's FY 2022 Appropriation
   - Carol Bergman, Vice President for Government Relations & Public Affairs
5. Presentation of LSC's Financial Report for the First Two Months of FY 2022
   - Debbie Moore, Chief Financial Officer and Treasurer
6. Discussion of LSC's FY 2023 Appropriations Request and Additional Supplemental Appropriation Requests
   - Carol Bergman, Vice President for Government Relations & Public Affairs
7. Public Comment
8. Consider and Act on Other Business
9. Consider and Act on Motion to Adjourn the Open Session Meeting and Proceed to a Closed Session Meeting

Closed Session

1. Review of Banking Services and Investment Policy
   - Debbie Moore, Chief Financial Officer and Treasurer
2. Consider and Act on Motion to Adjourn the Meeting

Audit Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Committee's Open Session Meeting on October 26, 2021
3. Discussion of the Committee's Evaluation for 2021 and the Committee's Goals for 2022
4. Briefing by the Office of Inspector General
   - Jeffrey Schanz, Inspector General
   - Roxanne Caruso, Assistant Inspector General for Audit
5. Pursuant to Section VIII(C)(5) of the Committee Charter, Review LSC's and the Office of Inspector General's Mechanisms for the Submission of Confidential Complaints
   - Dan O'Rourke, Assistant Inspector General for Investigation
   - Lora Rath, Director, Office of Compliance and Enforcement
6. Management Update Regarding Risk Management
   - Will Gunn, Vice President for Legal Affairs & General Counsel
7. Briefing about Follow-up by the Office of Compliance and Enforcement on Referrals by the Office of Inspector General Regarding Audit Reports and Annual Independent Public Audits of Grantees
   - Roxanne Caruso, Assistant Inspector General for Audit
   - Lora Rath, Director, Office of Compliance and Enforcement
8. Public Comment
9. Consider and Act on Other Business
10. Consider and Act on Motion to Adjourn the Open Session Meeting and Proceed to a Closed Session Meeting

Closed Session

1. Approval of Minutes of the Committee's Closed Session Meeting on October 26, 2021
2. Briefing by Office of Compliance and Enforcement on Active Enforcement matter(s) and Follow-Up to Open Investigation Referrals from the Office of Inspector General
   - Lora Rath, Director, Office of Compliance and Enforcement
3. Consider and Act on Adjournment of Meeting

Institutional Advancement Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Committee's Open Session Meeting on October 25, 2021
3. Discussion of the Committee's Evaluation for 2021 and the Committee's Goals for 2022
4. Update on Leaders Council and Emerging Leaders Council
   - John G. Levi, Chairman of the Board
5. Development Report
   - Nadia Elguindy, Director of Institutional Advancement
6. Consider and Act on Resolution #2022–XXX, Adopting Amendments to LSC's Fundraising Protocols
7. Consider and Act on Resolution #2022–XXX, Designating Use of Unrestricted Funds for LSC's *Talk Justice* Podcast
8. Update on LSC's 50th Anniversary Fundraising Campaign
   - Nadia Elguindy, Director of Institutional Advancement
   - Leo Latz, President and Founder, Latz & Company
9. Update on Veterans Task Force and Opioid Task Force Implementation
   - Stefanie Davis, Senior Assistant General Counsel and Ethics Officer
10. Update on Eviction Study
    - Lynn Jennings, Vice President for Grants Management
11. Update on Housing Task Force
    - Helen Guyton, Senior Assistant General Counsel
12. Update on Rural Justice Task Force
    - Jessica Wechter, Special Assistant to the President
13. Public Comment
14. Consider and Act on Other Business
15. Consider and Act on Motion to Adjourn the Open Session Meeting and Proceed to a Closed Session Meeting

Closed Session

1. Approval of Minutes of the Institutional Advancement Committee's Closed Session Meeting on October 25, 2021
2. Development Activities Report
   - Nadia Elguindy, Director of Institutional Advancement
3. Consider and Act on Motion to Approve Leaders Council and Emerging Leaders Council Invitees
4. Consider and Act on Other Business
5. Consider and Act on Motion to Adjourn the Meeting

Communications Subcommittee of the Institutional Advancement Committee

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Subcommittee's Open Session Meeting on October 25, 2021
3. Communications and Social Media Update
   - Carl Rauscher, Director of Communications and Media Relations
4. Public Comment
5. Consider and Act on Other Business
6. Consider and Act on Motion to Adjourn the Meeting

Delivery of Legal Services Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Committee's Open Session Meeting on October 25, 2021
3. Discussion of Committee's Evaluation for 2021 and the Committee's Goals for 2022
4. Review Delivery of Legal Services Committee Charter
5. Performance Criteria Update
   - Lynn Jennings, Vice President for Grants Management
   - Joyce McGee, Director, Office of Program Performance
6. Panel Discussion: Grantee Civil Legal Needs Assessments
   - Jon Asher, Executive Director, Colorado Legal Services
   - Colleen Cotter, Executive Director, The Legal Aid Society of Cleveland
   - Monica Vigues-Pitan, Executive Director, Legal Services of Miami
   - Moderator: Joyce McGee, Director, Office of Program Performance
7. Public Comment
8. Consider and Act on Other Business
9. Consider and Act on a Motion to Adjourn the Meeting

Board Meeting

Open Session

1. Pledge of Allegiance
2. Approval of Agenda
3. Approval of Minutes of the Board's Open Session Meetings on October 26 and November 22, 2021
4. Consider and Act on Nominations for the Chair of the Board of Directors
5. Consider and Act on Nominations for the Vice Chair of the Board of Directors
6. Chairman's Report
7. Members' Reports
8. President's Report
9. Inspector General's Report
10. Consider and Act on the Report of the Governance and Performance Review Committee
11. Consider and Act on the Report of the Operations and Regulations Committee
12. Consider and Act on the Report of the Finance Committee
13. Consider and Act on the Report of the Audit Committee
14. Consider and Act on the Report of the Institutional Advancement Committee
15. Consider and Act on the Report of the Delivery of Legal Services Committee
16. Public Comment
17. Consider and Act on Other Business
18. Consider and Act on Motion to Adjourn the Open Session Meeting and Proceed to a Closed Session Meeting

Closed Session

1. Approval of Minutes of the Board's Closed Session Meeting on October 26, 2021
2. Management Briefing
3. Inspector General Briefing
4. Consider and Act on General Counsel's Report on Potential and Pending Litigation Involving LSC
5. Consider and Act on Prospective Leaders Council and Emerging Leaders Council Invitees
6. Consider and Act on Motion to Adjourn the Meeting

CONTACT PERSON FOR MORE INFORMATION: Jessica Wechter, Special Assistant to the President, at (202) 295–1626. Questions may also be sent by electronic mail to *wechterj@lsc.gov.*

Non-Confidential Meeting Materials: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *https://www.lsc.gov/about-lsc/board-meeting-materials.*

Dated: January 13, 2022.

Jessica L. Wechter,

Special Assistant to the President, Legal Services Corporation.

[FR Doc. 2022–00999 Filed 1–14–22; 11:15 am]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Designation of Database for Treasury's Working System Under the Do Not Pay Initiative

AGENCY: Office of Management and Budget.

ACTION: Notice of designation.

SUMMARY: The Payment Integrity Information Act of 2019 (PIIA) authorizes the Office of Management and Budget (OMB) to designate databases for inclusion in Treasury's Working System under the Do Not Pay (DNP) Initiative. PIIA further requires OMB to provide public notice and opportunity for comment prior to designating additional databases. In fulfillment of this requirement, on October 12, 2021, OMB published a Notice of Proposed Designation (86 FR 56726) for the National Association of Public Health Statistics and Information Systems (NAPHSIS) Electronic Verification of Vital Events (EVVE) Facts of Death (FOD) System. OMB received no comments on this designation. Effective immediately, OMB designates the National Association of Public Health Statistics and Information Systems (NAPHSIS) Electronic Verification of Vital Events (EVVE) Facts of Death (FOD) System.

FOR FURTHER INFORMATION CONTACT: Regina Kearney at the OMB Office of Federal Financial Management at (202) 395–3993.

Shalanda Young,

Acting Director.

[FR Doc. 2022–00889 Filed 1–18–22; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–22–0001; NARA–2022–019]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: We must receive responses on the schedules listed in this notice by March 7, 2022.

ADDRESSES: To view a records schedule in this notice, or submit a comment on one, use the following address: *https://www.regulations.gov/docket/NARA-22-0001/document.* This is a direct link to the schedules posted in the docket for this notice on *regulations.gov.* You may submit comments by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have posted the records schedules open for comment. Each schedule has a 'comment' button so you can comment on that specific schedule. For more information on *regulations.gov* and on submitting comments, see their FAQs at *https://www.regulations.gov/faq.*

Due to COVID–19 building closures, we are currently temporarily not

accepting comments by mail. However, if you are unable to comment via *regulations.gov*, you may email us at *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at *regulation_comments@nara.gov.* For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule. We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Agriculture, Agricultural Marketing Service, Federal Milk Marketing Order Statistics Records (DAA–0136–2021–0007).
2. Department of Defense, Office of the Secretary of Defense, Office of People Analytics Survey Files (DAA–0330–2021–0008).
3. Department of Homeland Security, Science and Technology Directorate, Office of National Laboratories Records (DAA–0563–2019–0005).
4. Securities and Exchange Commission, Office of International Affairs, Case Files (DAA–0266–2021–0009).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2022–00933 Filed 1–18–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Notice per OMB Memoranda 22–08: Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act

AGENCY: National Foundation for the Arts and Humanities; National Endowment for the Arts.

ACTION: Notice of report.

SUMMARY: Per the ''Build America, Buy America Act'' (the ''Act''), federal entities are required to provide OMB and Congress a report listing all Federal financial assistance programs for infrastructure administered by the agency. This report is required to be published in the **Federal Register**. The NEA has no programs for infrastructure within the definition of the Act.

FOR FURTHER INFORMATION CONTACT: Brenna Berger, Director of Grants, National Endowment for the Arts, 400 7th St. SW, Washington, DC 20506, Telephone: 202–682–5400.

SUPPLEMENTARY INFORMATION: On November 15, 2021, President Biden signed into law the Infrastructure Investment and Jobs Act (IIJA), which includes the ''Build America, Buy America Act'' (the Act). This Act ensures that Federal infrastructure programs require the use of materials produced in the United States, increases

the requirement for American-made content, and strengthens the waiver process associated with Buy American provisions.

The Act requires that within 60 days of its enactment, each agency must submit to the Office of Management and Budget (OMB) and Congress a report (''60-day report'') listing all Federal financial assistance programs for infrastructure administered by the agency. In these 60-day reports, agencies are required to identify and provide a list of which of these programs are ''deficient,'' as defined in the Act. 3 These agency reports must also be published in the **Federal Register**.

The NEA has reviewed its Federal financial assistance programs and has determined that it does not administer any financial assistance programs for infrastructure as defined under the Act. Nor were any deficient programs, as defined under the Act, identified. This information has been reported to Congress and OMB as required by the Act.

Authority: 20 U.S.C. 959; Pub. L. 117–58 70913(a)(2).

Dated: January 13, 2022.

Meghan Jugder,

Support Services Specialist, Office of Administrative Services & Contracts National Endowment for the Arts.

[FR Doc. 2022–00926 Filed 1–18–22; 8:45 am]

BILLING CODE 7537–01–P

POSTAL REGULATORY COMMISSION

[Docket No. T2022–1; Order No. 6091]

Income Tax Review

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recent Postal Service filing concerning the calculation of the assumed Federal income tax on competitive products income for Fiscal Year 2021. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 3, 2022.

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

In accordance with 39 U.S.C. 3634 and 39 CFR 3060.40 *et seq.,* the Postal Service filed its calculation of the assumed Federal income tax on competitive products income for Fiscal Year (FY) 2021.[1] The calculation details the FY 2021 competitive product revenue and expenses, the competitive products net income before tax, and the assumed Federal income tax on that net income.

II. Notice of Commission Action

In accordance with 39 CFR 3060.42, the Commission establishes Docket No. T2022–1 to review the calculation of the assumed Federal income tax and supporting documentation.

The Commission invites comments on whether the Postal Service's filing in this docket is consistent with the policies of 39 U.S.C. 3634 and 39 CFR 3060.40 *et seq.* Comments are due no later than March 3, 2022. The Postal Service's filing can be accessed via the Commission's website (*http://www.prc.gov*).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. T2022–1 to consider the calculation of the assumed Federal income tax on competitive products for FY 2021.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than March 3, 2022.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–00931 Filed 1–18–22; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Notice of the United States Postal Service of Submission of the Calculation of the FY 2021 Assumed Federal Income Tax on Competitive Products, January 12, 2022.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93961; SR–MIAX–2022–03]

Self-Regulatory Organizations: Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange, LLC To Amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors

January 12, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 06, 2022, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to make a technical amendment to Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, to improve the operation of the Rule. Following discussions with other exchanges and a cross-section of industry participants and in coordination with the Listed Options Market Structure Working Group (''LOMSWG'') (collectively, the ''Industry Working Group''), the Exchange proposes: (1) To amend section (b)(3) of the Rule to permit the Exchange to determine the Theoretical Price [3] of a Customer [4] option transaction in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening; and (2) to amend section (c)(4)(B) of the Rule to adjust, rather than nullify, Customer transactions in Obvious Error situations, provided the adjustment does not violate the limit price, and to make a minor non-substantive change to the rule text to correct a typographical error.

Proposed Change to Section (b)(3)

Exchange Rule 521 has been part of various harmonization efforts by the Industry Working Group.[5] These efforts have often centered around the Theoretical Price for which an options transaction should be compared to determine whether an Obvious Error has occurred. For instance, all options exchanges have adopted language comparable to Interpretations and Policies .04, Exchange Determining Theoretical Price,[6] which explains how an exchange is to determine Theoretical Price at the open, when there are no valid quotes, and when there is a wide quote. This includes at times the use of a singular third-party vendor, known as a TP Provider (currently CBOE Livevol, LLC).

Similarly, section (b)(3) of Rule 521 was previously harmonized across all options exchanges to handle situations where executions occur in markets that are wide (as set forth in the rule).[7] Under that section, the Exchange determines the Theoretical Price if the NBBO [8] for the subject series is wide immediately before execution and a narrow market (as set forth in the rule) existed ''during the 10 seconds prior to the transaction.'' The rule goes on to clarify that, should there be no narrow quotes ''during the 10 seconds prior to the transaction,'' the Theoretical Price for the affected series is the NBBO that existed at the time of execution (regardless of its width).

In recent discussions, the Industry Working Group has identified proposed changes to section (b)(3) of Rule 521 that would improve the Rule's functioning. Currently, section (b)(3) does not permit the Exchange to determine the Theoretical Price unless there is a narrow quote 10 seconds prior to the transaction. However, in the first seconds of trading, there is no 10-second period ''prior to the transaction.'' Further, the Industry Working Group has observed that prices in certain series can be disjointed at the start of trading. Accordingly, the Exchange proposes to provide additional protections to trading in certain circumstances immediately after the opening before liquidity has had a chance to enter the market. The Exchange proposes to amend section (b)(3) to allow the Exchange to determine the Theoretical Price in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening.

Specifically, the Exchange proposes that the existing text of section (b)(3) would become subsection ''(A).'' The Exchange proposes to add the following heading and text as subsection ''(B)'':

(B) Customer Transactions Occurring Within 10 Seconds or Less After an Opening or Re-Opening:

(i) The Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction.

(ii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction, then the Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount anytime during the 10 seconds after an opening or re-opening.

(iii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds following an Opening or Re-Opening, then the Theoretical Price of an option series is the last NBB or NBO just prior to the Customer transaction in question, as set forth in paragraph (b) above.

(iv) Customer transactions occurring more than 10 seconds after an opening or re-opening are subject to paragraph A above.

The following examples illustrate the functioning of the proposed rule change. Consider that the NBBO of a series opens as $0.01 at $4.00. A marketable limit order to buy one contract arrives one second later and is executed at $4.00. In the third second of trading, the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within the 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review, in part due to the fact that there was only a single second of trading before the execution. Under the proposal, since a tight market existed at some point in the first 10 seconds of trading (*i.e.,* in the third second), the Exchange would be able to determine the Theoretical Price as provided in Interpretations and Policies .04.

As another example, the NBBO for a series opens as $0.01 at $4.00. In the seventh second of trading, a marketable limit order is received to buy one contract and is executed at $4.00. Five seconds later (*i.e.,* in the twelfth second of trading), the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review. Under the proposal, since no tight market existed at any point during the first 10 seconds of trading (*i.e.,* the narrow market occurred in the twelfth second), the trade would not qualify for obvious error review.

The proposed rule change would also better harmonize section (b)(3) with section (b)(1) of the Rule. Under section (b)(1), the Exchange is permitted to determine the Theoretical Price for transactions occurring as part of the opening auction process (as described in Exchange Rule 503) if there is no NBB

[3] *See* Exchange Rule 521(b).

[4] For purposes of Rule 521, the term ''Customer'' means a Priority Customer as defined in Rule 100. *See* Exchange Rule 521(a)(1).

[5] *See e.g.,* Securities Exchange Act Release Nos. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR–MIAX–2015–35); 80284 (March 21, 2017), 82 FR 15251 (March 27, 2017) (SR–MIAX–2017–13).

[6] *See* Securities Exchange Act Release No. 81321 (August 7, 2017), 82 FR 37633 (August 11, 2017) (SR–MIAX–2017–38).

[7] *See supra* note 5.

[8] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

or NBO for the affected series just prior to the erroneous transaction. However, under the current version of section (b)(3), a core trading transaction could occur in the same wide market but the Exchange would not be permitted to determine the Theoretical Price. Consider an example where one second after the Exchange opens a selected series, the NBBO is $1.00 at $5.00. At 9:30:03, a customer submits a marketable buy order to the Exchange and pays $5.00. At 9:30:03, a different exchange runs an opening auction that results in a customer paying $5.00 for the same selected series. At 9:30:06, the NBBO changes from $1.00 at $5.00 to $1.35 at $1.45. Under the current version of section (b)(3), the Exchange would not be able to determine the Theoretical Price for the trade occurring during core trading. However, the trade on the other exchange could be submitted for review under (b)(1) and that exchange would be able to determine the Theoretical Price. If the proposed change to section (b)(3) were approved, both of the trades occurring at 9:30:03 (on the Exchange during core trading and on another exchange via auction) would also be entitled to the same review regarding the same Theoretical Price based upon the same time.

The proposal would not change any obvious error review beyond the first 10 seconds of an opening or re-opening.

Proposed Change to Section (c)(4)(B)

The Exchange proposes to amend section (c)(4)(B)—the ''Adjust or Bust'' rule for Customer transactions in Obvious Error situations—to adjust rather than nullify such orders, provided the adjustment does not violate the Customer's limit price.

Currently, the Rule provides that in Obvious Error situations, transactions involving non-Customers should be adjusted, while transactions involving Customers are nullified, unless a certain condition applies.[9] The Industry Working Group has concluded that the treatment of these transactions should be harmonized under the Rule, such that transactions involving Customers may benefit from adjustment, just as non-Customer transactions currently do, except where such adjustment would violate the Customer's limit price; in that instance, the trade would be nullified.

Specifically, the Exchange proposes to amend the text of section (c)(4)(B) to add that where at least one party to the Obvious Error is a Customer, ''the execution price of the transaction will be adjusted by the Official pursuant to the table immediately above. Any Customer Obvious Error exceeding 50 contracts will be subject to the Size Adjustment Modifier defined in subparagraph (a)(4) above. However, if such adjustment(s) would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price,'' the trade will be nullified. The ''table immediately above'' referenced in the proposed text refers to the table at current Section (c)(4)(A), which provides for the adjustment of prices a specified amount away from the Theoretical Price, rather than adjusting the Theoretical Price.

The Exchange proposes no other changes at this time.

Implementation Date

The proposed rule change will become operative no sooner than six months following the approval of the NYSEArca proposal [10] to coincide with implementation on other option exchanges. The Exchange will announce the implementation date to its Members via Regulatory Circular.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(5) of the Act [12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change to section (b)(3) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because it provides a method for addressing Obvious Error Customer transactions that occur in a wide market at the opening of trading. Generally, a wide market is an indication of a lack of liquidity in the market such that the market is unreliable. Current section (b)(3) recognizes that a persistently wide quote (*i.e.,* more than 10 seconds) should be considered the reliable market regardless of its width, but does not address transactions that occur in a wide market in the first seconds of trading, where there is no preceding 10-second period to reference. Accordingly, in the first 10 seconds of trading, there is no opportunity for a wide quote to have persisted for a sufficiently lengthy period such that the market should consider it a reliable market for the purposes of determining an Obvious Error transaction.

The proposed change would rectify this disparity and permit the Exchange to consider whether a narrow quote is present at any time during the 10-second period after an opening or re-opening. The presence of such a narrow quote would indicate that the market has gained sufficient liquidity and that the previous wide market was unreliable, such that it would be appropriate for the Exchange to determine the Theoretical Price of an Obvious Error transaction. In this way, the proposed rule harmonizes the treatment of Customer transactions that execute in an unreliable market at any point of the trading day, by making them uniformly subject to Exchange determination of the Theoretical Price.

The Exchange believes that the proposed change to section (c)(4)(B) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by harmonizing the treatment of non-Customer transactions and Customer transactions under the Rule. Under the current Rule, Obvious Error situations involving non-Customer transactions are adjusted, while those involving Customer transactions are generally nullified, unless they meet the additional requirements of section (c)(4)(C) (*i.e.,* where a Member has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less). The proposal would harmonize the treatment of non-Customer and Customer transactions by providing for the adjustment of all such transactions, except where such

[9] Specifically, the current Rule provides at section (c)(4)(C) that if any Member has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less, where at least one party to the Obvious Error is a non-Customer, then the Exchange will apply the non-Customer adjustment criteria set forth in (c)(4)(A) for such transactions.

[10] *See* Securities Exchange Act Release No. 93818 (December 17, 2021), 86 FR 73009 (December 23, 2021) (SR–NYSEArca–2021–91) (Order Approving a Proposed Rule Change to Amend Rule 6.87–O).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

adjustment would violate the Customer's limit price.

When it proposed the current rule in 2015, the Exchange believed there were sound reasons for treating non-Customer transactions and Customer transactions differently. At the time, the Exchange stated its belief that ''Customers are not necessarily immersed in the day-to-day trading of the markets, are less likely to be watching trading activity in a particular option throughout the day, and may have limited funds in their trading accounts,'' and that nullifying Obvious Error transactions involving Customers would give Customers ''greater protections'' than adjusting such transactions by eliminating the possibility that a Customer's order will be adjusted to a significantly different price. The Exchange also noted its belief that ''Customers are . . . less likely to have engaged in significant hedging or other trading activity based on earlier transactions, and thus, are less in need of maintaining a position at an adjusted price than non-Customers.'' [13]

Those assumptions about Customer trading and hedging activity no longer hold. The Exchange and the Industry Working Group believe that over the course of the last five years, Customers that use options have become more sophisticated, as retail broker-dealers have enhanced the trading tools available. Pursuant to OCC data, volumes clearing in the Customer range have expanded from 12,022,163 ADV in 2015 to 35,081,130 ADV in 2021. This increase in trading activity underscores the greater understanding of options by Customers as a trading tool and its use in the markets. Customers who trade options today largely are more educated, have better trading tools, and have better access to financial news than any time prior.[14] The proposed rule would extend the hedging protections currently enjoyed by non-Customers to Customers, by allowing them to maintain an option position at an adjusted price, which would in turn prevent a cascading effect by maintaining the hedge relationship between the option transaction and any other transactions in a related security.

The Exchange believes that extending such hedging protections to Customer transactions would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by providing greater certainty of execution for all participants to options transactions. Under the current Rule, a Customer that believes its transaction was executed pursuant to an Obvious Error may be disincentivized from submitting the transaction for review, since during the review process, the Customer would be uncertain whether the trade would be nullified, and if so, whether market conditions would still permit the opportunity to execute a related order at a better price after the nullification ruling is finalized. In contrast, under the proposed rule, the Customer would know that the only likely outcomes of submitting a trade to Obvious Error review would be that the trade would stand or be re-executed at a better price; the trade would only be nullified if the adjustment would violate the order's limit. Similarly, under the current Rule, during the review period, a market maker who traded contra to the Customer would be uncertain if it should retain any position executed to hedge the original trade, or attempt to unwind it, possibly at a significant loss. Under the proposed rule change, this uncertainty is largely eliminated, and the question would be whether the already-executed and hedged trade would be adjusted to a better price for the Customer, or if it would stand as originally executed. In this way, the proposed rule enhances the protection of investors and removes impediments to and perfects the mechanism of a free and open market and a national market system.

The proposed rule also addresses the concern the Exchange cited in its 2015 filing that adjusting, rather than nullifying, Customer transactions could lead to a Customer's order being adjusted to a significantly different price. To address that concern, the proposed rule would prevent Customer transactions from being adjusted to a price that violates the order's limit; if the adjustment would violate a Customer's limit, the trade would instead be nullified. The Exchange believes it is in the best interest of investors to expand the availability of adjustments to Customer transactions in all Obvious Error situations except where the adjustment would violate the Customer's limit price.

Further, the Exchange believes that, with respect to such proposed adjustments to Customer transactions, it is appropriate to use the same form of adjustment as is currently in place with respect to non-Customer transactions as laid out in the table in section (c)(4)(A). That is, the Exchange believes that it is appropriate to adjust to prices a specified amount away from the Theoretical Price rather than to adjust the Theoretical Price, even though the Exchange has determined a given trade to be erroneous in nature, because the parties in question should have had some expectation of execution at the price or prices submitted. Also, it is common that by the time it is determined that an Obvious Error has occurred, additional hedging and trading activity has already occurred based on the executions that previously happened. The Exchange believes that providing an adjustment to the Theoretical Price in all cases would not appropriately incentivize market participants to maintain appropriate controls to avoid potential errors, while adjusting to prices a specified amount away from the Theoretical Price would incentivize such behavior.

The Exchange believes that the proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed change to section (b)(3) would apply to all instances of a wide market occurring within the first 10 seconds of trading followed by a narrow market at any point in the subsequent 10-second period, regardless of the types of market participants involved in such transactions. The proposed change to section (c)(4)(B) would harmonize the treatment of Obvious Error transactions involving Customers and non-Customers, no matter what type of market participants those parties may be.

The Exchange believes the proposed non-substantive change promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system because the proposed change corrects a typographical error and will provide greater clarity to Members and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[15] The Exchange anticipates that the other options exchanges will adopt substantively similar proposals, such

[13] *See* Securities Exchange Act Release No. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR–MIAX–2015–35).

[14] Dan Raju, *Retail Traders Adopt Options En Masse,* by Dan Raju, (Dec 8, 2020) available at *https://www.nasdaq.com/articles/retail-traders-adopt-options-en-masse-2020-12-08.*

[15] 15 U.S.C. 78f(b)(8).

that there would be no burden on intermarket competition from the Exchange's proposal. Accordingly, the proposed change is not meant to affect competition among the options exchanges. For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) [17] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2022–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2022–03. 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–MIAX–2022–03 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00874 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93964; File No. SR–CboeEDGX–2022–001]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

January 12, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 4, 2022, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'' or ''EDGX Equities'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''EDGX Equities'') to (1) modify the criteria of Growth Tier 4, and (2) adopt a new Retail Growth Tier 1, effective January 3, 2022.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[3] no single registered equities exchange has more than 18% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays rebates to members that add liquidity and assesses fees to those that remove liquidity. The Exchange's Fee Schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity. For orders in securities priced below $1.00, the Exchange provides a standard rebate of $0.00009 per share for orders that add liquidity and assesses a fee of 0.30% of total dollar value for orders that remove liquidity. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Under footnote 1 of the Fee Schedule, the Exchange currently offers various Add/Remove Volume Tiers. In particular, the Exchange offers four Growth Tiers that each provide an enhanced rebate for Members' qualifying orders yielding fee codes B,[4] V,[5] Y,[6] 3 [7] and 4,[8] where a Member reaches certain add volume-based criteria, including ''growing'' its volume over a certain baseline month. Currently, Growth Tier 4 is as follows:

- Growth Tier 4 provides a rebate of $0.0034 per share to qualifying orders (*i.e.,* orders yielding fee codes B, V, Y, 3, or 4) where (1) the Member adds a Step-Up ADAV from October 2021 equal to or greater than 0.10% of the TCV or the Member adds a Step-Up ADAV from October 2021 equal to or greater than 10 million shares; and (2) the Member has a total remove ADV equal to or greater than 0.60% of TCV.

Now, the Exchange proposes to amend the second prong of the criteria. Specifically, proposed Growth Tier 4 is as follows:

- Proposed Growth Tier 4 provides a rebate of $0.0034 per share to qualifying orders (*i.e.,* orders yielding fee codes B, V, Y, 3, or 4) where (1) the Member adds a Step-Up ADAV from October 2021 equal to or greater than 0.10% of the TCV or the Member adds a Step-Up ADAV from October 2021 equal to or greater than 10 million shares; and (2) the Member has a total remove ADV equal to or greater than 0.60% of TCV or the Member has a total remove ADV equal to or greater than 60 million shares.

The proposed modification to Growth Tier 4 is designed to provide Members an additional opportunity to meet the tier.

Under footnote 2 of the Fee Schedule, the Exchange currently offers various Retail Volume Tiers, which provide an enhanced rebate for Members' qualifying orders yielding fee code ZA.[9] Now, the Exchange proposes to adopt a Retail Growth Tier 1, which would provide for the same required criteria as Growth Tier 4, as modified. Specifically, the proposed Retail Growth Tier 1 is as follows:

- Proposed Growth Tier 4 [sic] provides a rebate of $0.0034 per share to qualifying orders (*i.e.,* orders yielding fee code ZA) where (1) the Member adds a Step-Up ADAV from October 2021 equal to or greater than 0.10% of the TCV or the Member adds a Step-Up ADAV from October 2021 equal to or greater than 10 million shares; and (2) the Member has a total remove ADV equal to or greater than 0.60% of TCV or the Member has a total remove ADV equal to or greater than 60 million shares.

The proposed Retail Growth Tier 1 is designed to provide Members an opportunity to receive an enhanced rebate by meeting the Retail Growth Tier 1 criteria. Further, overall the Growth Tiers are intended to provide Members an opportunity to receive an enhanced rebate by increasing their order flow to the Exchange, which further contributes to a deeper, more liquid market and provides even more execution opportunities for active market participants. Incentivizing an increase in liquidity adding or removing volume, through enhanced rebate opportunities, encourages liquidity adding Members on the Exchange to contribute to a deeper, more liquid market, and liquidity executing Members on the Exchange to increase transactions and take execution opportunities provided by such increased liquidity, together providing for overall enhanced price discovery and price improvement opportunities on the Exchange. As such, increased overall order flow benefits all Members by contributing towards a robust and well-balanced market ecosystem.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[10] in general, and furthers the objectives of Section 6(b)(4),[11] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged

[3] See Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (December 20, 2021), available at *https://markets.cboe.com/us/equities/market_statistics/.*

[4] Orders yielding Fee Code ''B'' are orders adding liquidity to EDGX (Tape B).

[5] Orders yielding Fee Code ''V'' are orders adding liquidity to EDGX (Tape A).

[6] Orders yielding Fee Code ''Y'' are orders adding liquidity to EDGX (Tape C).

[7] Orders yielding Fee Code ''3'' are orders adding liquidity to EDGX in the pre and post market (Tapes A or C).

[8] Orders yielding Fee Code ''4'' are orders adding liquidity to EDGX in the pre and post market (Tape B).

[9] Orders yielding Fee Code ''ZA'' are retail orders adding liquidity to EDGX.

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78f.(b)(5).

in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[13] including the Exchange,[14] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

In particular, the Exchange believes Growth Tier 4, as modified, and the proposed Retail Growth Tier 1 are reasonable because they will be available to all Members and provide all Members with an additional opportunity to receive an enhanced rebate. The Exchange further believes the proposed Growth Tier 4 and Retail Growth Tier 1 will provide a reasonable means to encourage overall and retail growth, respectively, in Members' order flow to the Exchange and to incentivize Members to continue to provide liquidity adding and removing volume to the Exchange by offering them an additional opportunity to receive an enhanced rebate on qualifying orders. An overall increase in activity would deepen the Exchange's liquidity pool, offers additional cost savings, support the quality of price discovery, promote market transparency and improve market quality, for all investors.

Further, the Exchange believes that the proposed changes are reasonable as it does not represent a significant departure from the criteria currently offered in the Fee Schedule. Specifically, the proposed change to Growth Volume Tier 4 merely adds additional criteria to achieve the Tier, and the proposed Retail Growth Tier 1 is nearly identical to the Growth Volume Tier 4, as modified. Additionally, the Exchange believes that the enhanced rebates under Growth Tier 4, which is not being changed, and the Proposed Retail Growth Tier 1 is commensurate with the criteria.

The Exchange also believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members will be eligible for Growth Tier 4 and the proposed Retail Growth Tier 1 and have the opportunity to meet the Tiers' criteria and receive the corresponding enhanced rebate if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for Growth Tier 4, as amended, or the proposed Retail Growth Tier 1. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, the Exchange anticipates that at least one Member will be able to satisfy the criteria proposed under each tier. The Exchange also notes that proposed changes will not adversely impact any Member's ability to qualify for reduced fees or enhanced rebates offered under other tiers. Should a Member not meet the proposed new criteria, the Member will merely not receive that corresponding enhanced rebate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes to Growth Tier 4 and the proposed Retail Growth Tier 1 will apply to all Members equally in that all Members are eligible for each of the Tiers, have a reasonable opportunity to meet the Tiers' criteria and will receive the enhanced rebate on their qualifying orders if such criteria is met. The Exchange does not believe the proposed changes burdens competition, but rather, enhances competition as it is intended to increase the competitiveness of EDGX by amending an existing pricing incentive and adopting a pricing incentive in order to attract order flow and incentivize participants to increase their participation on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 18% of the market share.[15] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission

[13] *See* BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[14] *See* EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[15] *Supra* note 1.

has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [16] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[17] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [18] and paragraph (f) of Rule 19b–4 [19] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2022–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2022–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2022–001, and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00877 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[16] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[17] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93962; SR–EMERALD–2022–01]

Self-Regulatory Organizations: Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by MIAX Emerald, LLC To Amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors

January 12, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 7, 2022, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a technical amendment to Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald* at MIAX Emerald's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, to improve the operation of the Rule. Following discussions with other exchanges and a cross-section of industry participants and in coordination with the Listed Options Market Structure Working Group (''LOMSWG'') (collectively, the ''Industry Working Group''), the Exchange proposes: (1) To amend section (b)(3) of the Rule to permit the Exchange to determine the Theoretical Price [3] of a Customer [4] option transaction in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening; and (2) to amend section (c)(4)(B) of the Rule to adjust, rather than nullify, Customer transactions in Obvious Error situations, provided the adjustment does not violate the limit price.

Proposed Change to Section (b)(3)

Exchange Rule 521 has been part of various harmonization efforts by the Industry Working Group.[5] These efforts have often centered around the Theoretical Price for which an options transaction should be compared to determine whether an Obvious Error has occurred. For instance, all options exchanges have adopted language comparable to Interpretations and Policies .04, Exchange Determining Theoretical Price,[6] which explains how an exchange is to determine Theoretical Price at the open, when there are no valid quotes, and when there is a wide quote. This includes at times the use of a singular third-party vendor, known as a TP Provider (currently CBOE Livevol, LLC).

Similarly, section (b)(3) of Rule 521 was previously harmonized across all options exchanges to handle situations where executions occur in markets that are wide (as set forth in the rule).[7] Under that section, the Exchange determines the Theoretical Price if the NBBO [8] for the subject series is wide immediately before execution and a narrow market (as set forth in the rule) existed ''during the 10 seconds prior to the transaction.'' The rule goes on to clarify that, should there be no narrow quotes ''during the 10 seconds prior to the transaction,'' the Theoretical Price for the affected series is the NBBO that existed at the time of execution (regardless of its width).

In recent discussions, the Industry Working Group has identified proposed changes to section (b)(3) of Rule 521 that would improve the Rule's functioning. Currently, section (b)(3) does not permit the Exchange to determine the Theoretical Price unless there is a narrow quote 10 seconds prior to the transaction. However, in the first seconds of trading, there is no 10-second period ''prior to the transaction.'' Further, the Industry Working Group has observed that prices in certain series can be disjointed at the start of trading. Accordingly, the Exchange proposes to provide additional protections to trading in certain circumstances immediately after the opening before liquidity has had a chance to enter the market. The Exchange proposes to amend section (b)(3) to allow the Exchange to determine the Theoretical Price in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening.

Specifically, the Exchange proposes that the existing text of section (b)(3) would become subsection ''(A).'' The Exchange proposes to add the following heading and text as subsection ''(B)'':

(B) Customer Transactions Occurring Within 10 Seconds or Less After an Opening or Re-Opening:

(i) The Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction.

(ii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction, then the Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount anytime during the 10 seconds after an opening or re-opening.

(iii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds following an Opening or Re-Opening, then the Theoretical Price of an option series is the last NBB or NBO just prior to the Customer transaction in question, as set forth in paragraph (b) above.

(iv) Customer transactions occurring more than 10 seconds after an opening or re-opening are subject to paragraph A above.

The following examples illustrate the functioning of the proposed rule change. Consider that the NBBO of a series opens as $0.01 at $4.00. A marketable limit order to buy one contract arrives one second later and is executed at $4.00. In the third second of trading, the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within the 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review, in part due to the fact that there was only a single second of trading before the execution. Under the proposal, since a tight market existed at some point in the first 10 seconds of trading (*i.e.,* in the third second), the Exchange would be able to determine the Theoretical Price as provided in Interpretations and Policies .04.

As another example, the NBBO for a series opens as $0.01 at $4.00. In the seventh second of trading, a marketable limit order is received to buy one contract and is executed at $4.00. Five seconds later (*i.e.,* in the twelfth second of trading), the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review. Under the proposal, since no tight market existed at any point during the first 10 seconds of trading (*i.e.,* the narrow market occurred in the twelfth second), the trade would not qualify for obvious error review.

[3] *See* Exchange Rule 521(b).

[4] For purposes of Rule 521, the term ''Customer'' means a Priority Customer as defined in Rule 100. *See* Exchange Rule 521(a)(1).

[5] *See e.g.,* Securities Exchange Act Release Nos. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR–MIAX–2015–35); 80284 (March 21, 2017), 82 FR 15251 (March 27, 2017) (SR–MIAX–2017–13).

[6] *See* Securities Exchange Act Release No. 81321 (August 7, 2017), 82 FR 37633 (August 11, 2017) (SR–MIAX–2017–38).

[7] *See supra* note 5.

[8] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

The proposed rule change would also better harmonize section (b)(3) with section (b)(1) of the Rule. Under section (b)(1), the Exchange is permitted to determine the Theoretical Price for transactions occurring as part of the opening auction process (as described in Exchange Rule 503) if there is no NBB or NBO for the affected series just prior to the erroneous transaction. However, under the current version of section (b)(3), a core trading transaction could occur in the same wide market but the Exchange would not be permitted to determine the Theoretical Price. Consider an example where one second after the Exchange opens a selected series, the NBBO is $1.00 at $5.00. At 9:30:03, a customer submits a marketable buy order to the Exchange and pays $5.00. At 9:30:03, a different exchange runs an opening auction that results in a customer paying $5.00 for the same selected series. At 9:30:06, the NBBO changes from $1.00 at $5.00 to $1.35 at $1.45. Under the current version of section (b)(3), the Exchange would not be able to determine the Theoretical Price for the trade occurring during core trading. However, the trade on the other exchange could be submitted for review under (b)(1) and that exchange would be able to determine the Theoretical Price. If the proposed change to section (b)(3) were approved, both of the trades occurring at 9:30:03 (on the Exchange during core trading and on another exchange via auction) would also be entitled to the same review regarding the same Theoretical Price based upon the same time.

The proposal would not change any obvious error review beyond the first 10 seconds of an opening or re-opening.

Proposed Change to Section (c)(4)(B)

The Exchange proposes to amend section (c)(4)(B)—the ''Adjust or Bust'' rule for Customer transactions in Obvious Error situations—to adjust rather than nullify such orders, provided the adjustment does not violate the Customer's limit price.

Currently, the Rule provides that in Obvious Error situations, transactions involving non-Customers should be adjusted, while transactions involving Customers are nullified, unless a certain condition applies.[9] The Industry Working Group has concluded that the treatment of these transactions should be harmonized under the Rule, such that transactions involving Customers may benefit from adjustment, just as non-Customer transactions currently do, except where such adjustment would violate the Customer's limit price; in that instance, the trade would be nullified.

Specifically, the Exchange proposes to amend the text of section (c)(4)(B) to add that where at least one party to the Obvious Error is a Customer, ''the execution price of the transaction will be adjusted by the Official pursuant to the table immediately above. Any Customer Obvious Error exceeding 50 contracts will be subject to the Size Adjustment Modifier defined in subparagraph (a)(4) above. However, if such adjustment(s) would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price,'' the trade will be nullified. The ''table immediately above'' referenced in the proposed text refers to the table at current Section (c)(4)(A), which provides for the adjustment of prices a specified amount away from the Theoretical Price, rather than adjusting the Theoretical Price.

The Exchange proposes no other changes at this time.

Implementation Date

The proposed rule change will become operative no sooner than six months following the approval of the NYSEArca proposal[10] to coincide with implementation on other option exchanges. The Exchange will announce the implementation date to its Members via Regulatory Circular.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[11] in general, and furthers the objectives of Section 6(b)(5) of the Act[12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change to section (b)(3) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because it provides a method for addressing Obvious Error Customer transactions that occur in a wide market at the opening of trading. Generally, a wide market is an indication of a lack of liquidity in the market such that the market is unreliable. Current section (b)(3) recognizes that a persistently wide quote (*i.e.,* more than 10 seconds) should be considered the reliable market regardless of its width, but does not address transactions that occur in a wide market in the first seconds of trading, where there is no preceding 10-second period to reference. Accordingly, in the first 10 seconds of trading, there is no opportunity for a wide quote to have persisted for a sufficiently lengthy period such that the market should consider it a reliable market for the purposes of determining an Obvious Error transaction.

The proposed change would rectify this disparity and permit the Exchange to consider whether a narrow quote is present at any time during the 10-second period after an opening or re-opening. The presence of such a narrow quote would indicate that the market has gained sufficient liquidity and that the previous wide market was unreliable, such that it would be appropriate for the Exchange to determine the Theoretical Price of an Obvious Error transaction. In this way, the proposed rule harmonizes the treatment of Customer transactions that execute in an unreliable market at any point of the trading day, by making them uniformly subject to Exchange determination of the Theoretical Price.

The Exchange believes that the proposed change to section (c)(4)(B) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by harmonizing the treatment of non-Customer transactions and Customer transactions under the Rule. Under the current Rule, Obvious Error situations involving non-Customer transactions are adjusted, while those involving Customer transactions are generally nullified, unless they meet the additional requirements of section (c)(4)(C) (*i.e.,* where a Member has 200 or more Customer transactions under review concurrently and the orders

[9] Specifically, the current Rule provides at section (c)(4)(C) that if any Member has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less, where at least one party to the Obvious Error is a non-Customer, then the Exchange will apply the non-Customer adjustment criteria set forth in (c)(4)(A) for such transactions.

[10] *See* Securities Exchange Act Release No. 93818 (December 17, 2021), 86 FR 73009 (December 23, 2021) (SR–NYSEArca–2021–91) (Order Approving a Proposed Rule Change to Amend Rule 6.87–O).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

resulting in such transactions were submitted during the course of 2 minutes or less.) The proposal would harmonize the treatment of non-Customer and Customer transactions by providing for the adjustment of all such transactions, except where such adjustment would violate the Customer's limit price.

When the current rule was proposed in 2015, the MIAX Options Exchange believed there were sound reasons for treating non-Customer transactions and Customer transactions differently. At the time, the MIAX Options Exchange stated its belief that ''Customers are not necessarily immersed in the day-to-day trading of the markets, are less likely to be watching trading activity in a particular option throughout the day, and may have limited funds in their trading accounts,'' and that nullifying Obvious Error transactions involving Customers would give Customers ''greater protections'' than adjusting such transactions by eliminating the possibility that a Customer's order will be adjusted to a significantly different price. The Exchange also noted its belief that ''Customers are . . . less likely to have engaged in significant hedging or other trading activity based on earlier transactions, and thus, are less in need of maintaining a position at an adjusted price than non-Customers.'' [13]

Those assumptions about Customer trading and hedging activity no longer hold. The Exchange and the Industry Working Group believe that over the course of the last five years, Customers that use options have become more sophisticated, as retail broker-dealers have enhanced the trading tools available. Pursuant to OCC data, volumes clearing in the Customer range have expanded from 12,022,163 ADV in 2015 to 35,081,130 ADV in 2021. This increase in trading activity underscores the greater understanding of options by Customers as a trading tool and its use in the markets. Customers who trade options today largely are more educated, have better trading tools, and have better access to financial news than any time prior.[14] The proposed rule would extend the hedging protections currently enjoyed by non-Customers to Customers, by allowing them to maintain an option position at an adjusted price, which would in turn prevent a cascading effect by maintaining the hedge relationship between the option transaction and any other transactions in a related security.

The Exchange believes that extending such hedging protections to Customer transactions would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by providing greater certainty of execution for all participants to options transactions. Under the current Rule, a Customer that believes its transaction was executed pursuant to an Obvious Error may be disincentivized from submitting the transaction for review, since during the review process, the Customer would be uncertain whether the trade would be nullified, and if so, whether market conditions would still permit the opportunity to execute a related order at a better price after the nullification ruling is finalized. In contrast, under the proposed rule, the Customer would know that the only likely outcomes of submitting a trade to Obvious Error review would be that the trade would stand or be re-executed at a better price; the trade would only be nullified if the adjustment would violate the order's limit. Similarly, under the current Rule, during the review period, a market maker who traded contra to the Customer would be uncertain if it should retain any position executed to hedge the original trade, or attempt to unwind it, possibly at a significant loss. Under the proposed rule change, this uncertainty is largely eliminated, and the question would be whether the already-executed and hedged trade would be adjusted to a better price for the Customer, or if it would stand as originally executed. In this way, the proposed rule enhances the protection of investors and removes impediments to and perfects the mechanism of a free and open market and a national market system.

The proposed rule also addresses the concern the Exchange cited in its 2015 filing that adjusting, rather than nullifying, Customer transactions could lead to a Customer's order being adjusted to a significantly different price. To address that concern, the proposed rule would prevent Customer transactions from being adjusted to a price that violates the order's limit; if the adjustment would violate a Customer's limit, the trade would instead be nullified. The Exchange believes it is in the best interest of investors to expand the availability of adjustments to Customer transactions in all Obvious Error situations except where the adjustment would violate the Customer's limit price.

Further, the Exchange believes that, with respect to such proposed adjustments to Customer transactions, it is appropriate to use the same form of adjustment as is currently in place with respect to non-Customer transactions as laid out in the table in section (c)(4)(A). That is, the Exchange believes that it is appropriate to adjust to prices a specified amount away from the Theoretical Price rather than to adjust the Theoretical Price, even though the Exchange has determined a given trade to be erroneous in nature, because the parties in question should have had some expectation of execution at the price or prices submitted. Also, it is common that by the time it is determined that an Obvious Error has occurred, additional hedging and trading activity has already occurred based on the executions that previously happened. The Exchange believes that providing an adjustment to the Theoretical Price in all cases would not appropriately incentivize market participants to maintain appropriate controls to avoid potential errors, while adjusting to prices a specified amount away from the Theoretical Price would incentivize such behavior.

The Exchange believes that the proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed change to section (b)(3) would apply to all instances of a wide market occurring within the first 10 seconds of trading followed by a narrow market at any point in the subsequent 10-second period, regardless of the types of market participants involved in such transactions. The proposed change to section (c)(4)(B) would harmonize the treatment of Obvious Error transactions involving Customers and non-Customers, no matter what type of market participants those parties may be.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[15] The Exchange anticipates that the other options exchanges will adopt substantively similar proposals, such that there would be no burden on intermarket competition from the Exchange's proposal. Accordingly, the proposed change is not meant to affect

[13] *See* Securities Exchange Act Release No. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR–MIAX–2015–35).

[14] Dan Raju, *Retail Traders Adopt Options En Masse,* by Dan Raju, (Dec 8, 2020) available at *https://www.nasdaq.com/articles/retail-traders-adopt-options-en-masse-2020-12-08.*

[15] 15 U.S.C. 78f(b)(8).

competition among the options exchanges. For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) [17] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EMERALD–2022–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–EMERALD–2022–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EMERALD–2022–01 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00875 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93965; File No. SR–PEARL–2022–02]

Self-Regulatory Organizations: Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by MIAX PEARL, LLC To Amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors

January 12, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 7, 2022 MIAX PEARL, LLC (''MIAX Pearl'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposed rule to make a technical amendment to Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, to improve the operation of the Rule. Following discussions with other exchanges and a cross-section of industry participants and in coordination with the Listed Options Market Structure Working Group (''LOMSWG'') (collectively, the ''Industry Working Group''), the Exchange proposes: (1) To amend section (b)(3) of the Rule to permit the Exchange to determine the Theoretical Price [3] of a Customer [4] option transaction in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening; and (2) to amend section (c)(4)(B) of the Rule to adjust, rather than nullify, Customer transactions in Obvious Error situations, provided the adjustment does not violate the limit price.

Proposed Change to Section (b)(3)

Exchange Rule 521 has been part of various harmonization efforts by the Industry Working Group.[5] These efforts have often centered around the Theoretical Price for which an options transaction should be compared to determine whether an Obvious Error has occurred. For instance, all options exchanges have adopted language comparable to Interpretations and Policies .03, Exchange Determining Theoretical Price,[6] which explains how an exchange is to determine Theoretical Price at the open, when there are no valid quotes, and when there is a wide quote. This includes at times the use of a singular third-party vendor, known as a TP Provider (currently CBOE Livevol, LLC).

Similarly, section (b)(3) of Rule 521 was previously harmonized across all options exchanges to handle situations where executions occur in markets that are wide (as set forth in the rule).[7] Under that section, the Exchange determines the Theoretical Price if the NBBO [8] for the subject series is wide immediately before execution and a narrow market (as set forth in the rule) existed ''during the 10 seconds prior to the transaction.'' The rule goes on to clarify that, should there be no narrow quotes ''during the 10 seconds prior to the transaction,'' the Theoretical Price for the affected series is the NBBO that existed at the time of execution (regardless of its width).

In recent discussions, the Industry Working Group has identified proposed changes to section (b)(3) of Rule 521 that would improve the Rule's functioning. Currently, section (b)(3) does not permit the Exchange to determine the Theoretical Price unless there is a narrow quote 10 seconds prior to the transaction. However, in the first seconds of trading, there is no 10-second period ''prior to the transaction.'' Further, the Industry Working Group has observed that prices in certain series can be disjointed at the start of trading. Accordingly, the Exchange proposes to provide additional protections to trading in certain circumstances immediately after the opening before liquidity has had a chance to enter the market. The Exchange proposes to amend section (b)(3) to allow the Exchange to determine the Theoretical Price in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening.

Specifically, the Exchange proposes that the existing text of section (b)(3) would become subsection ''(A).'' The Exchange proposes to add the following heading and text as subsection ''(B)'':

(B) Customer Transactions Occurring Within 10 Seconds or Less After an Opening or Re-Opening:

(i) The Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction.

(ii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction, then the Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer's erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount anytime during the 10 seconds after an opening or re-opening.

(iii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds following an Opening or Re-Opening, then the Theoretical Price of an option series is the last NBB or NBO just prior to the Customer transaction in question, as set forth in paragraph (b) above.

(iv) Customer transactions occurring more than 10 seconds after an opening or re-opening are subject to paragraph A above.

The following examples illustrate the functioning of the proposed rule change. Consider that the NBBO of a series opens as $0.01 at $4.00. A marketable limit order to buy one contract arrives one second later and is executed at $4.00. In the third second of trading, the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within the 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review, in part due to the fact that there was only a single second of trading before the execution. Under the proposal, since a tight market existed at some point in the first 10 seconds of trading (*i.e.,* in the third second), the Exchange would be able to determine the Theoretical Price as provided in Interpretations and Policies .04.

As another example, the NBBO for a series opens as $0.01 at $4.00. In the seventh second of trading, a marketable limit order is received to buy one contract and is executed at $4.00. Five seconds later (*i.e.,* in the twelfth second of trading), the NBBO narrows from $0.01 at $4.00 to $2.00 at $2.10. While the execution occurred in a market with wide widths, there was no tight market within 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review. Under the proposal, since no tight market existed at any point during the first 10 seconds of trading (*i.e.,* the narrow market occurred in the twelfth second), the trade would not qualify for obvious error review.

The proposed rule change would also better harmonize section (b)(3) with section (b)(1) of the Rule. Under section (b)(1), the Exchange is permitted to determine the Theoretical Price for transactions occurring as part of the opening auction process (as described in Exchange Rule 503) if there is no NBB or NBO for the affected series just prior to the erroneous transaction. However, under the current version of section (b)(3), a core trading transaction could occur in the same wide market but the

[3] *See* Exchange Rule 521(b).

[4] For purposes of Rule 521, the term ''Customer'' means a Priority Customer as defined in Rule 100. See Exchange Rule 521(a)(1).

[5] *See e.g.,* Securities Exchange Act Release No. 81324 (August 7, 2017), 82 FR 37618 (August 11, 2017) (SR–PEARL–2017–33).

[6] *Id.*

[7] *See supra* note 5.

[8] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

Exchange would not be permitted to determine the Theoretical Price. Consider an example where one second after the Exchange opens a selected series, the NBBO is $1.00 at $5.00. At 9:30:03, a customer submits a marketable buy order to the Exchange and pays $5.00. At 9:30:03, a different exchange runs an opening auction that results in a customer paying $5.00 for the same selected series. At 9:30:06, the NBBO changes from $1.00 at $5.00 to $1.35 at $1.45. Under the current version of section (b)(3), the Exchange would not be able to determine the Theoretical Price for the trade occurring during core trading. However, the trade on the other exchange could be submitted for review under (b)(1) and that exchange would be able to determine the Theoretical Price. If the proposed change to section (b)(3) were approved, both of the trades occurring at 9:30:03 (on the Exchange during core trading and on another exchange via auction) would also be entitled to the same review regarding the same Theoretical Price based upon the same time.

The proposal would not change any obvious error review beyond the first 10 seconds of an opening or re-opening.

Proposed Change to Section (c)(4)(B)

The Exchange proposes to amend section (c)(4)(B)—the ''Adjust or Bust'' rule for Customer transactions in Obvious Error situations—to adjust rather than nullify such orders, provided the adjustment does not violate the Customer's limit price.

Currently, the Rule provides that in Obvious Error situations, transactions involving non-Customers should be adjusted, while transactions involving Customers are nullified, unless a certain condition applies.[9] The Industry Working Group has concluded that the treatment of these transactions should be harmonized under the Rule, such that transactions involving Customers may benefit from adjustment, just as non-Customer transactions currently do, except where such adjustment would violate the Customer's limit price; in that instance, the trade would be nullified.

Specifically, the Exchange proposes to amend the text of section (c)(4)(B) to add that where at least one party to the Obvious Error is a Customer, ''the execution price of the transaction will be adjusted by the Official pursuant to the table immediately above. Any Customer Obvious Error exceeding 50 contracts will be subject to the Size Adjustment Modifier defined in subparagraph (a)(4) above. However, if such adjustment(s) would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price,'' the trade will be nullified. The ''table immediately above'' referenced in the proposed text refers to the table at current Section (c)(4)(A), which provides for the adjustment of prices a specified amount away from the Theoretical Price, rather than adjusting the Theoretical Price.

The Exchange proposes no other changes at this time.

Implementation Date

The proposed rule change will become operative no sooner than six months following the approval of the NYSEArca proposal [10] to coincide with implementation on other option exchanges. The Exchange will announce the implementation date to its Members via Regulatory Circular.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(5) of the Act [12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change to section (b)(3) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because it provides a method for addressing Obvious Error Customer transactions that occur in a wide market at the opening of trading. Generally, a wide market is an indication of a lack of liquidity in the market such that the market is unreliable. Current section (b)(3) recognizes that a persistently wide quote (*i.e.,* more than 10 seconds) should be considered the reliable market regardless of its width, but does not address transactions that occur in a wide market in the first seconds of trading, where there is no preceding 10-second period to reference. Accordingly, in the first 10 seconds of trading, there is no opportunity for a wide quote to have persisted for a sufficiently lengthy period such that the market should consider it a reliable market for the purposes of determining an Obvious Error transaction.

The proposed change would rectify this disparity and permit the Exchange to consider whether a narrow quote is present at any time during the 10-second period after an opening or re-opening. The presence of such a narrow quote would indicate that the market has gained sufficient liquidity and that the previous wide market was unreliable, such that it would be appropriate for the Exchange to determine the Theoretical Price of an Obvious Error transaction. In this way, the proposed rule harmonizes the treatment of Customer transactions that execute in an unreliable market at any point of the trading day, by making them uniformly subject to Exchange determination of the Theoretical Price.

The Exchange believes that the proposed change to section (c)(4)(B) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by harmonizing the treatment of non-Customer transactions and Customer transactions under the Rule. Under the current Rule, Obvious Error situations involving non-Customer transactions are adjusted, while those involving Customer transactions are generally nullified, unless they meet the additional requirements of section (c)(4)(C) (*i.e.,* where a Member has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less.) The proposal would harmonize the treatment of non-Customer and Customer transactions by providing for the adjustment of all such transactions, except where such adjustment would violate the Customer's limit price.

When the current rule was proposed in 2015, the MIAX Options Exchange believed there were sound reasons for

[9] Specifically, the current Rule provides at section (c)(4)(C) that if any Member has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less, where at least one party to the Obvious Error is a non-Customer, then the Exchange will apply the non-Customer adjustment criteria set forth in (c)(4)(A) for such transactions.

[10] *See* Securities Exchange Act Release No. 93818 (December 17, 2021), 86 FR 73009 (December 23, 2021) (SR–NYSEArca–2021–91) (Order Approving a Proposed Rule Change to Amend Rule 6.87–O).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

treating non-Customer transactions and Customer transactions differently. At the time, the MIAX Options Exchange stated its belief that ''Customers are not necessarily immersed in the day-to-day trading of the markets, are less likely to be watching trading activity in a particular option throughout the day, and may have limited funds in their trading accounts,'' and that nullifying Obvious Error transactions involving Customers would give Customers ''greater protections'' than adjusting such transactions by eliminating the possibility that a Customer's order will be adjusted to a significantly different price. The MIAX Options Exchange also noted its belief that ''Customers are . . . less likely to have engaged in significant hedging or other trading activity based on earlier transactions, and thus, are less in need of maintaining a position at an adjusted price than non-Customers.'' [13]

Those assumptions about Customer trading and hedging activity no longer hold. The Exchange and the Industry Working Group believe that over the course of the last five years, Customers that use options have become more sophisticated, as retail broker-dealers have enhanced the trading tools available. Pursuant to OCC data, volumes clearing in the Customer range have expanded from 12,022,163 ADV in 2015 to 35,081,130 ADV in 2021. This increase in trading activity underscores the greater understanding of options by Customers as a trading tool and its use in the markets. Customers who trade options today largely are more educated, have better trading tools, and have better access to financial news than any time prior.[14] The proposed rule would extend the hedging protections currently enjoyed by non-Customers to Customers, by allowing them to maintain an option position at an adjusted price, which would in turn prevent a cascading effect by maintaining the hedge relationship between the option transaction and any other transactions in a related security.

The Exchange believes that extending such hedging protections to Customer transactions would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by providing greater certainty of execution for all participants to options transactions. Under the current Rule, a Customer that believes its transaction was executed pursuant to an Obvious Error may be disincentivized from submitting the transaction for review, since during the review process, the Customer would be uncertain whether the trade would be nullified, and if so, whether market conditions would still permit the opportunity to execute a related order at a better price after the nullification ruling is finalized. In contrast, under the proposed rule, the Customer would know that the only likely outcomes of submitting a trade to Obvious Error review would be that the trade would stand or be re-executed at a better price; the trade would only be nullified if the adjustment would violate the order's limit. Similarly, under the current Rule, during the review period, a market maker who traded contra to the Customer would be uncertain if it should retain any position executed to hedge the original trade, or attempt to unwind it, possibly at a significant loss. Under the proposed rule change, this uncertainty is largely eliminated, and the question would be whether the already-executed and hedged trade would be adjusted to a better price for the Customer, or if it would stand as originally executed. In this way, the proposed rule enhances the protection of investors and removes impediments to and perfects the mechanism of a free and open market and a national market system.

The proposed rule also addresses the concern the MIAX Options Exchange cited in its 2015 filing that adjusting, rather than nullifying, Customer transactions could lead to a Customer's order being adjusted to a significantly different price. To address that concern, the proposed rule would prevent Customer transactions from being adjusted to a price that violates the order's limit; if the adjustment would violate a Customer's limit, the trade would instead be nullified. The Exchange believes it is in the best interest of investors to expand the availability of adjustments to Customer transactions in all Obvious Error situations except where the adjustment would violate the Customer's limit price.

Further, the Exchange believes that, with respect to such proposed adjustments to Customer transactions, it is appropriate to use the same form of adjustment as is currently in place with respect to non-Customer transactions as laid out in the table in section (c)(4)(A). That is, the Exchange believes that it is appropriate to adjust to prices a specified amount away from the Theoretical Price rather than to adjust the Theoretical Price, even though the Exchange has determined a given trade to be erroneous in nature, because the parties in question should have had some expectation of execution at the price or prices submitted. Also, it is common that by the time it is determined that an Obvious Error has occurred, additional hedging and trading activity has already occurred based on the executions that previously happened. The Exchange believes that providing an adjustment to the Theoretical Price in all cases would not appropriately incentivize market participants to maintain appropriate controls to avoid potential errors, while adjusting to prices a specified amount away from the Theoretical Price would incentivize such behavior.

The Exchange believes that the proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed change to section (b)(3) would apply to all instances of a wide market occurring within the first 10 seconds of trading followed by a narrow market at any point in the subsequent 10-second period, regardless of the types of market participants involved in such transactions. The proposed change to section (c)(4)(B) would harmonize the treatment of Obvious Error transactions involving Customers and non-Customers, no matter what type of market participants those parties may be.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[15] The Exchange anticipates that the other options exchanges will adopt substantively similar proposals, such that there would be no burden on intermarket competition from the Exchange's proposal. Accordingly, the proposed change is not meant to affect competition among the options exchanges. For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

[13] *See* Securities Exchange Act Release No. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR–MIAX–2015–35).

[14] Dan Raju, *Retail Traders Adopt Options En Masse,* by Dan Raju, (Dec 8, 2020) available at *https://www.nasdaq.com/articles/retail-traders-adopt-options-en-masse-2020-12-08.*

[15] 15 U.S.C. 78f(b)(8).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) [17] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2022–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2022–02. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2022–02 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00878 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93954; File No. SR–MEMX–2021–20]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 15.1(e) Regarding FINRA Registration and Processing Fees

January 12, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 29, 2021, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

(a) The Exchange is filing with the Commission a proposed rule change to amend Exchange Rule 15.1(e) to reflect adjustments to the Financial Industry Regulatory Authority, Inc. (''FINRA'') Registration and Processing Fees related to the Central Registration Depository System (''CRD system''), which will be collected by FINRA. While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on January 3, 2022.[3] The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Today, Exchange Rule 15.1(e) provides a list of FINRA Registration and Processing Fees that will be collected and retained by FINRA via the CRD system. The Exchange does not collect or retain these fees. The Exchange is proposing to amend Exchange Rule 15.1(e) to reflect adjustments to FINRA's Registration and Processing Fees related to the CRD

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR–FINRA–2020–032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adjust FINRA Fees To Provide Sustainable Funding for FINRA's Regulatory Mission) (the ''FINRA Fee Filing'').

system.[4] FINRA charges a single fee to register any representative or principal of a member firm in the CRD system irrespective of if the member firm is also a member of FINRA. Because FINRA separately collects the CRD system fee for any Member [5] that is also a FINRA member,[6] this fee filing only applies to Members who are not FINRA members.

Effective January 3, 2022, FINRA is increasing the fee it charges for each initial Form U4 filed for the registration of a representative or principal of any firm registered in the CRD system from $100 to $125.[7] Accordingly, the Exchange is proposing to update Exchange Rule 15.1(e) to reflect the new $125 CRD system fee that will take effect starting January 3, 2022. Because these costs are borne by FINRA when a non-FINRA member uses the CRD system, FINRA will continue to collect and retain these fees for the registration of associated persons of Members that are not also FINRA members.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[8] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. All similarly situated Members are subject to the same fee structure, and every Member firm must use the CRD system for registration and disclosure.

The proposed fee is reasonable because it is identical to the fee adopted by FINRA for use of the CRD system for disclosure and the registration of associated persons of FINRA members.[10] Thus, the Exchange Rule 15.1(e) will reflect the current registration rate that will be assessed by FINRA as of January 3, 2022 for any Members that are not also FINRA members. The Exchange also believes the proposed fee change is reasonable, because, as noted in the FINRA Fee Filing, FINRA is increasing the CRD system fees to provide enough revenue to support its regulatory mission.[11] Notably, FINRA has not increased CRD system fees since 2012.[12]

The Exchange believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 is equitable and not unfairly discriminatory because the equivalent fees will be charged by FINRA of all users of the CRD system, whether or not they are FINRA members. Therefore, all users of the CRD system will equally bear the cost of maintaining the system.[13]

FINRA further noted its belief that the proposed fees are reasonable because they help to ensure the integrity of the information in the CRD system, which is important because the Commission, FINRA, other self-regulatory organizations and state securities regulators use the CRD system to make licensing and registration decisions, among other things.[14]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that the proposed fees will result in the same regulatory fees being charged to all Members required to report information to the CRD system and for services performed by FINRA, regardless of whether or not such Members are FINRA members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [15] and Rule 19b–4(f)(2) [16] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MEMX–2021–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2021–20. 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; the Commission does not edit personal identifying information from submissions. You should submit only

[4] The CRD system is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker dealers.

[5] *See* Exchange Rule 1.5(p).

[6] Members that are also FINRA members are charged CRD system fees according to Section (4) of Schedule A to the FINRA By-Laws.

[7] *See supra* note 3.

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4) and (5).

[10] *See supra* note 3.

[11] *See supra* note 3.

[12] *See supra* note 3.

[13] *See supra* note 3.

[14] *See supra* note 3.

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2021–20 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–00870 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93968; File No. SR–EMERALD–2021–46]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

January 12, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 29, 2021, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Emerald Fee Schedule (the ''Fee Schedule'') to reflect adjustments to the Financial Industry Regulatory Authority (''FINRA'') Registration Fees.[3]

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments to become operative on January 2, 2022.[4]

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 2)c) of the Fee Schedule, Web CRD Fees, to reflect adjustments to the FINRA Registration Fees.[5] The FINRA fees are collected and retained by FINRA via Web Central Registration Depository (''CRD'') for the registration of associated persons of MIAX Emerald Electronic Exchange Member[6] and Market Maker[7] organizations that are not also FINRA members (''Non-FINRA members'').[8] The Exchange merely lists these fees in its Fee Schedule. The Exchange does not collect or retain these fees.

Since March 1, 2019, FINRA has assessed, and the Exchange has listed in its Fee Schedule, a $100 fee for the FINRA CRD processing fee.[9] This fee is for all initial, transfer, relicense, and dual registration Form U4 filings.[10] This fee is assessed when a non-FINRA firm (*i.e.,* a firm that is not a member of FINRA) submits its first initial, transfer, relicense, or dual registration Form U4 filing on behalf of a registered person.[11]

The Exchange now proposes to amend, under the General Registration Fees in Section 2)c) of the Fee Schedule, the FINRA CRD Processing Fee from $100 to $125 for each initial Form U4 filed for the registration of a representative or principal. This amendment is made in accordance with a recent FINRA rule change to adjust its fees.[12]

The FINRA fees are collected and retained by FINRA via Web CRD for the registration of employees of the Exchange who are Non-FINRA members. The FINRA Web CRD Fees are user-based, and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA. The Exchange merely lists these fees in its Fee Schedule. The Exchange does not collect or retain these fees.

Implementation

The proposed rule change will become operative on January 2, 2022.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[13] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes it is reasonable to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 in accordance with an adjustment to

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Fee Schedule, Section 2)c).

[4] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR–FINRA–2020–032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Adjust FINRA Fees to Provide Sustainable Funding for FINRA's Regulatory Mission).

[5] *Id.*

[6] ''Electronic Exchange Member'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[7] ''Market Makers'' means ''Lead Market Maker,'' ''Primary Lead Market Maker'' and ''Registered Market Maker'' collectively. *See* Exchange Rule 100.

[8] *See* Securities Exchange Act Release No. 85393 (March 21, 2019), 84 FR 11599 (March 27, 2019) (SR–EMERALD–2019–15).

[9] *See id.*

[10] *Id.*

[11] *Id.*

[12] *Id.* FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the qualification, employment and disciplinary histories of registered associated persons of broker-dealers. FINRA noted in its rule change that it was adjusting its fees to provide sustainable funding for FINRA's regulatory mission.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *Id.*

FINRA's fees. The Exchange's rule text will reflect the current registration rate that will be assessed by FINRA as of January 2, 2022. The proposed fee change is identical to that adopted by FINRA for use of Web CRD for the registration of FINRA members and their associated persons. These costs are borne by FINRA when a Non-FINRA member uses Web CRD.

The Exchange believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 is equitable and not unfairly discriminatory as the amendment will reflect the current fee that will be assessed by FINRA to all members who require Form U4 filings as of January 2, 2022. Further, the proposal is also equitable and not unfairly discriminatory because the Exchange will not be collecting or retaining these fees; therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. The proposed rule change was based on recent fee adjustments currently assessed by FINRA.[16] Thus, the proposed change does not raise any new or novel issues. For these reasons, the Exchange believes that the proposal is consistent with the Act.

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 believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 does not impose an undue burden on competition as the amendment will reflect the current fee that will be assessed by FINRA to all members who require Form U4 filings as of January 2, 2022. Further, the proposal does not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees; therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[16] *See supra* note 4.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2) [18] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email *to rule-comments@sec.gov.* Please include File Number SR–EMERALD–2021–46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–EMERALD–2021–46. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EMERALD–2021–46 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00881 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93963; File Nos. SR–CboeBYX–2021–027; SR–CboeBZX–2021–076; SR–CboeEDGA–2021–024; SR–CboeEDGX–2021–048]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Cboe BZX Exchange, Inc.; Cboe EDGA Exchange, Inc.; Cboe EDGX Exchange, Inc.; Order Granting Approval of Proposed Rule Changes To Amend Each Exchange's Rules in Connection With a Risk Setting That Users May Elect To Apply to Their Orders in Hard To Borrow Securities

January 12, 2022.

I. Introduction

On November 8, 2021, Cboe BYX Exchange, Inc. (''CboeBYX'') and Cboe BZX Exchange, Inc. (''CboeBZX''), and on November 18, 2021, Cboe EDGA Exchange, Inc. (''CboeEDGA'') and Cboe EDGX Exchange, Inc. (''CboeEDGX,'' and collectively, the ''Exchanges''), each 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 allow each Exchange to offer its Users [3] a hard to borrow risk setting

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A User is any Member or Sponsored Participant who is authorized to obtain access to the System. *See* Cboe BYX Rule 1.5(cc); Cboe BZX Rule 1.5(cc);

Continued

(''Hard to Borrow List'') that Users may elect to apply to their short sale orders in U.S. equity securities. The proposed rule changes were published for comment in the **Federal Register** on November 29, 2021.[4]

The Commission has received no comments on the proposed rule changes. This order approves the proposed rule changes.

II. Description of the Proposed Rule Changes

The Exchanges propose to include a Hard to Borrow List within their risk settings. The Exchanges currently offer certain optional risk settings applicable to a User's activities on the Exchange.[5] These risk settings currently provide Users with controls to restrict the types of securities transacted, including restricted securities and easy to borrow securities, as well as restricting activity to test symbols only.[6]

According to the Exchanges, when utilized, these optional risk tools act as a risk filter by evaluating a User's orders to determine whether the orders comply with certain criteria established by the User.[7] The proposal will offer Users an optional tool to evaluate whether their orders comply with User established criteria.[8] Specifically, orders submitted in securities included on a User's Hard to Borrow List will be rejected back to the User.[9] The Hard to Borrow List resides at a User's port level, a User-specific logical session used to access the Exchange.[10] Users may upload a Hard to Borrow List to their preferred port(s) via a web-based application programming interface.[11] When uploaded to the port, Users may apply the setting to some or all of the market-participant identifiers (MPID) that they use to access the Exchange via the specified port.[12]

The Exchanges state that, as is the case with the Exchanges' existing risk settings, the User, and not the Exchange, will have the full responsibility for ensuring that their orders comply with applicable securities rules, laws, and regulations, and may not rely on the Hard to Borrow List for any such purpose.[13] Furthermore, use of the Hard to Borrow List does not automatically constitute compliance with Exchange Rules.[14] The Exchanges state that they do not believe that the use of the Hard to Borrow List can replace User-managed risk management solutions.[15]

The Exchanges propose to make the risk setting available to their Users upon request and will not require Users to utilize the Hard to Borrow List.[16] The Exchanges also state that they will not provide preferential treatment to Users using the Hard to Borrow List.[17]

In support of the proposal, the Exchanges assert the Hard to Borrow List will offer Users another option in efficient risk management of their access to the Exchange.[18] For example, the Exchanges state the Hard to Borrow List may assist some Users in managing borrowing costs for their short sale transactions.[19] According to the Exchanges, day over day borrowing costs in hard to borrow securities may be costly, and while a locate may be secured by a User prior to routing their short sale transactions to one of the Exchanges, borrowing costs may make such transactions less desirable.[20] The Exchanges state by utilizing the Hard to Borrow List, Users have a tool that enables them to manage their costs by rejecting orders in such securities.[21]

III. Discussion and Commission Findings

After careful review of the proposals, the Commission finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[22] In particular, the Commission finds that the proposed rule changes are consistent with Section 6(b)(5) of the Act,[23] which requires, among other things, that the Exchanges' rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that the proposed rule changes are reasonably designed to provide a useful risk management tool to Users on the Exchanges. Adding a Hard to Borrow List could allow Users on the Exchanges to better manage borrowing costs for such securities. The Exchanges currently provide risk controls restricting certain transactions by symbol,[24] and the Commission believes that the proposed rule change would provide an additional option for Users seeking to further tailor their risk management capability while transacting on the Exchanges.

The Commission notes that the proposed Hard to Borrow List is an optional functionality. The Commission reminds Users electing to use the proposed risk control to be mindful of their obligations under all applicable securities laws, rules, and regulations and emphasizes that the proposed risk control is not a substitute for a Users' own systems, processes, and procedures for compliance with such laws, rules, and regulations. The Commission expects the Exchanges to periodically assess whether its risk control settings are operating in a manner that is consistent with the promotion of fair and orderly markets.

For the foregoing reasons, the Commission finds that the proposal is consistent with the requirements of the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [25] that the proposed rule changes (SR–CboeBYX–2021–027, SR–CboeBZX–2021–076, SR–CboeEDGA–2021–024, SR–CboeEDGX–

Cboe EDGA Rule 1.5(ee); and Cboe EDGX Rule 1.5(ee).

[4] *See* Securities Exchange Act Release Nos. 93638 (November 22, 2021), 86 FR 67767 (SR–CboeBYX–2021–027) (''BYX Notice''); 93641 (November 22, 2021), 86 FR 67763 (SR–CboeBZX–2021–076) (''BZX Notice''); 93642 (November 22, 2021), 86 FR 67765 (SR–CboeEDGA–2021–024) (''EDGA Notice''); and 93643 (November 22, 2021), 86 FR 67774 (SR–CboeEDGX–2021–048) (''EDGX Notice''). The proposed rule changes are nearly identical.

[5] *See* Interpretation and Policy .01 to CboeBYX Rule 11.13; Interpretation and Policy .01 to CboeBZX Rule 11.13; Interpretation and Policy .01 to CboeEDGA Rule 11.10; and Interpretation and Policy .01 to CboeEDGX Rule 11.10.

[6] *See* BYX Notice at 67767; BZX Notice at 67764; EDGA Notice at 67765; and EDGX Notice at 67775.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *See* BYX Notice at 67767; BZX Notice at 67764; EDGA Notice at 67765; and EDGX Notice at 67775 (citing Securities and Exchange Act Release No. 50103 (July 28 2004), 69 FR 48007 (August 6, 2004) (Final Rule: Short Sales) at 48014, regarding hard to borrow lists and the locate requirements under 17 CFR 242.203 (Regulation SHO Rule 203—Borrowing and delivery requirements)).

[14] *See* BYX Notice at 67767; BZX Notice at 67764; EDGA Notice at 67766; and EDGX Notice at 67775.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] In approving the proposed rule changes, the Commission notes that it has considered the proposed rules' impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 15 U.S.C. 78f(b)(5).

[24] *See, e.g.,* Interpretation and Policy .01 to CboeBYX Rule 11.13(d); Interpretation and Policy .01 to CboeBZX Rule 11.13(d); Interpretation and Policy .01 to CboeEDGA Rule 11.10(d); and Interpretation and Policy .01 to CboeEDGX Rule 11.10(d).

[25] 15 U.S.C. 78f(b)(5).

2021–048), be, and hereby are, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00876 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93969; File No. SR–MIAX–2021–64]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by To Amend Its Fee Schedule

January 12, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 29, 2021, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to reflect adjustments to the Financial Industry Regulatory Authority (''FINRA'') Registration Fees.[3]

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments to become operative on January 2, 2022.[4]

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be exa mined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 2)c) of the Fee Schedule, Web CRD Fees, to reflect adjustments to the FINRA Registration Fees.[5] The FINRA fees are collected and retained by FINRA via Web Central Registration Depository (''CRD'') for the registration of associated persons of MIAX Electronic Exchange Member[6] and Market Maker[7] organizations that are not also FINRA members (''Non-FINRA members'').[8] The Exchange merely lists these fees in its Fee Schedule. The Exchange does not collect or retain these fees.

Since January 2, 2013, FINRA has assessed, and the Exchange has listed in its Fee Schedule, a $100 fee for the FINRA CRD process [sic] fee.[9] This fee is for all initial, transfer, relicense, and dual registration Form U4 filings.[10] This fee is assessed when a non-FINRA firm (*i.e.,* a firm that is not a member of FINRA) submits its first initial, transfer, relicense, or dual registration Form U4 filing on behalf of a registered person.[11]

The Exchange now proposes to amend, under the General Registration Fees in Section 2)c) of the Fee Schedule, the FINRA CRD Processing Fee from $100 to $125 for each initial Form U4 filed for the registration of a representative or principal. This amendment is made in accordance with a recent FINRA rule change to adjust its fees.[12]

The FINRA fees are collected and retained by FINRA via Web CRD for the registration of employees of the Exchange who are Non-FINRA members. The FINRA Web CRD Fees are user-based, and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA. The Exchange merely lists these fees in its Fee Schedule. The Exchange does not collect or retain these fees.

Implementation

The proposed rule change will become operative on January 2, 2022.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[13] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes it is reasonable to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 in accordance with an adjustment to FINRA's fees. The Exchange's rule text

[26] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Fee Schedule, Section 2)c).

[4] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR–FINRA–2020–032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Adjust FINRA Fees to Provide Sustainable Funding for FINRA's Regulatory Mission).

[5] *Id.*

[6] ''Electronic Exchange Member'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[7] ''Market Makers'' means ''Lead Market Makers,'' ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[8] *See* Securities Exchange Act Release No. 68415 (December 12, 2012), 77 FR 74905 (December 18, 2012) (SR–MIAX–2012–01).

[9] *See id.*

[10] *Id.*

[11] *Id.*

[12] *Id.* FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the qualification, employment and disciplinary histories of registered associated persons of broker-dealers. FINRA noted in its rule change that it was adjusting its fees to provide sustainable funding for FINRA's regulatory mission.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *Id.*

will reflect the current registration rate that will be assessed by FINRA as of January 2, 2022. The proposed fee change is identical to that adopted by FINRA for use of Web CRD for the registration of FINRA members and their associated persons. These costs are borne by FINRA when a Non-FINRA member uses Web CRD.

The Exchange believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 is equitable and not unfairly discriminatory as the amendment will reflect the current fee that will be assessed by FINRA to all members who require Form U4 filings as of January 2, 2022. Further, the proposal is also equitable and not unfairly discriminatory because the Exchange will not be collecting or retaining these fees; therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. The proposed rule change was based on recent fee adjustments currently assessed by FINRA.[16] Thus, the proposed change does not raise any new or novel issues. For these reasons, the Exchange believes that the proposal is consistent with the Act.

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 believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 does not impose an undue burden on competition as the amendment will reflect the current fee that will be assessed by FINRA to all members who require Form U4 filings as of January 2, 2022. Further, the proposal does not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees; therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[16] *See supra* note 4.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2) [18] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2021–64 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2021–64. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–MIAX–2021–64 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–00882 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93960; File No. SR–NYSEArca–2021–109]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges

January 12, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 30, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to adopt an alternative requirement to qualify for the Tape B Tier 3 pricing tier. The Exchange proposes to implement the fee change effective January 3, 2022. The proposed rule change is available on the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt an alternative requirement to qualify for the Tape B Tier 3 pricing tier. The Exchange proposes to implement the fee change effective January 3, 2022.

Background

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [3]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [4] Indeed, equity trading is currently dispersed across 16 exchanges,[5] numerous alternative trading systems,[6] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly available information, no single exchange currently has more than 18% market share.[7] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange currently has less than 12% market share of executed volume of equities trading.[8]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products. While it is not possible to know a firm's reason for shifting order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange venues to which a firm routes order flow. With respect to non-marketable order flow that would provide liquidity on an Exchange against which market makers can quote, ETP Holders can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange.

Proposed Rule Change

Currently, under the Tape B Tier 3 pricing tier, an ETP Holder could qualify for a credit of $0.0025 per share [9] for adding liquidity in Tape B Securities if such ETP Holder (1) has Adding ADV of Tape B CADV that is equal to at least 0.20% of the Tape B CADV and (2) has Market Maker Electronic Posting Volume of TCADV of at least 0.50% by an OTP Holder or OTP Firm affiliated with the ETP Holder.

The Exchange proposes to adopt an alternative requirement to qualify for Tape B Tier 3 credit. As proposed, an ETP Holder could qualify for the Tape B Tier 3 credit of $0.0025 per share for adding liquidity in Tape B securities if such ETP Holder has Adding ADV of Tape B CADV that is equal to at least 0.15% over the ETP Holder's April 2020 Adding ADV taken as a percentage of Tape B CADV.

The Exchange is not proposing any change to the level of Tape B Tier 3 credits.

The proposed rule change to adopt an alternative requirement to qualify for the existing credit is designed to incentivize ETP Holders to increase liquidity-providing orders in Tape B securities they send to the Exchange, which would support the quality of price discovery on the Exchange and provide additional liquidity for incoming orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of

[3] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (''Regulation NMS'').

[4] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[5] *See* Cboe U.S Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[6] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is available at *https://www.sec.gov/foia/docs/atslist.htm.*

[7] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[8] *See id.*

[9] Under Section III of the Fee Schedule—Standard Rates, ETP Holders receive a credit of $0.0020 per share for orders that add liquidity in Tape B securities. Additionally, in securities priced at or above $1.00, an additional credit in Tape B securities may be available to LMMs and to Market Makers affiliated with LMMs that add displayed liquidity based on the number of Less Active ETP Securities in which the LMM is registered as the LMM. The applicable tiered-credits are noted in the Fee Schedule under LMM Transaction Fees and Credits.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

products, in response to fee changes. With respect to non-marketable orders that provide liquidity on an Exchange, ETP Holders can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces reasonably constrain exchange transaction fees that relate to orders that would provide displayed liquidity on an exchange. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

In particular, the Exchange believes the proposed rule change is reasonable because it provides an additional opportunity for ETP Holders to receive an existing rebate on qualifying orders in a manner that incentivizes order flow on the Exchange's equities platform. The Exchange believes the proposed change to adopt an alternative requirement to qualify for the Tape B Tier 3 pricing tier is reasonable because it provides ETP Holders with an additional way to qualify for the pricing tier's credit by providing liquidity in Tape B securities each month over a predetermined baseline, and which does not include an options component. The Exchange believes that the proposed alternative to qualify for the pricing tier utilizing an equities-only requirement is reasonable because the proposal provides firms that do not have an affiliation with an OTP Holder or OTP Firm the ability to reach the proposed volume tier by sending liquidity providing orders in tape B securities, thereby creating an incentive for ETP Holders to bring increased order flow to a public exchange.

The Exchange believes the proposed change to adopt an alternative method to qualify for existing credits is reasonable as these changes would provide an incentive for ETP Holders to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the existing credit, thereby contributing to depth and market quality on the Exchange.

As noted above, the Exchange operates in a highly competitive environment, particularly for attracting order flow that provides displayed liquidity on an exchange. More specifically, the Exchange notes that greater add volume order flow may provide for deeper, more liquid markets and execution opportunities at improved prices, which the Exchange believes would incentivize liquidity providers to submit additional liquidity and enhance execution opportunities.

The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and not unfairly discriminatory because they are available to all ETP Holders on an equal basis. They also provide additional benefits or discounts that are reasonably related to the value of the Exchange's market quality and associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, the Exchange is one of many venues and off-exchange venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. Competing exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based on members achieving certain volume thresholds.

The Exchange believes its proposal equitably allocates its fees and credits among its market participants.

The Exchange believes that the proposal represents an equitable allocation of fees and credits and is not unfairly discriminatory because it would apply uniformly to all ETP Holders, in that all ETP Holders will be eligible for the existing credit and have the opportunity to meet the tier's criteria and receive the applicable rebate if such criteria is met. The existing rebate would apply automatically and uniformly to all ETP Holders that achieve the corresponding criteria. The proposed change is designed as an incentive to any and all liquidity providers interested in meeting the tier criteria to submit order flow to the Exchange and each will receive the associated rebate if the tier criteria is met. While the Exchange has no way of knowing whether this proposed rule change would definitively result in any particular ETP Holder qualifying for the existing credit by utilizing the proposed alternative requirement, the Exchange anticipates a number of ETP Holders would be able to meet, or will reasonably be able to meet, the proposed criteria. However, without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any ETP Holder meeting the alternative requirement and qualifying for the Tape B Tier 3 rebate. As stated, the proposed alternative requirement to qualify for an existing credit is designed to provide an incentive for ETP Holders to submit additional liquidity in Tape B securities.

The Exchange believes that the proposal is not unfairly discriminatory.

The Exchange believes it is not unfairly discriminatory to provide an alternative way to qualify for the per share credit under the Tape B Tier 3 pricing tier, as the credit would be provided on an equal basis to all ETP Holders that meet the proposed alternative requirement. Further, the Exchange believes the proposed alternative requirement would incentivize ETP Holders to send their liquidity providing orders in Tape B securities to the Exchange to qualify for the existing rebate.

The Exchange believes that the proposed alternative requirement to qualify for the Tape B Tier 3 credit is not unfairly discriminatory because it would be available to all ETP Holders on an equal and non-discriminatory basis. In this regard, the Exchange notes that ETP Holders that do not meet the proposed alternative requirement would continue to have the opportunity to qualify for the Tape B Tier 3 credit by satisfying the current requirement, which would not change as a result of this proposal.

The Exchange also believes that the proposed rule change is not unfairly discriminatory because it is reasonably related to the value to the Exchange's market quality associated with higher volume. The proposed change to the Tape B Tier 3 pricing tier is designed as an incentive to any and all ETP Holders interested in meeting the tier criteria to submit additional order flow to the Exchange and each will receive the existing rebate if the tier criteria is met. The Exchange also notes that the proposed rule change will not adversely impact any ETP Holder's pricing or its ability to qualify for other tiers. Rather, should an ETP Holder not meet the Tape B Tier 3 pricing tier's criteria, the ETP Holder will merely not receive the corresponding rebate.

In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Moreover, this proposed rule change neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that this proposal does not permit unfair discrimination because the changes described in this proposal would be applied uniformly to all similarly situated ETP Holders and all ETP Holders would be subject to the same requirements. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by the proposed allocation of fees. The Exchange further believes that the proposed changes would not permit unfair discrimination among ETP Holders because the Tape B Tier 3 credit

would be available equally to all ETP Holders.

Finally, the submission of orders to the Exchange is optional for ETP Holders in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard. The Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for ETP Holders. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [14]

Intramarket Competition. The Exchange believes the proposed amendment to its Fee Schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or its competitors. The proposed change is designed to attract additional order flow to the Exchange, in particular with respect to Tape B securities. The Exchange believes that the proposed adoption of an alternative requirement to qualify for an established credit under the Tape B Tier 3 pricing tier would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage ETP Holders to send orders to the Exchange, thereby contributing towards a robust and well-balanced market ecosystem.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As noted above, the Exchange's market share of intraday trading (*i.e.,* excluding auctions) is currently less than 12%. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [15] of the Act and subparagraph (f)(2) of Rule 19b–4 [16] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [17] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–109 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–2021–109. 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 offices 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

[13] 15 U.S.C. 78f(b)(8).

[14] *See* Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(2).

[17] 15 U.S.C. 78s(b)(2)(B).

submissions should refer to File Number SR–NYSEArca–2021–109, and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00873 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93967; File No. SR–EMERALD–2021–45]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

January 12, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 30, 2021, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Emerald Fee Schedule (the ''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 1(a)(i) of the Fee Schedule to: (i) Decrease Simple Maker (as defined below) rebates in certain Tiers for options transactions in Penny classes (as defined below) for the Market Maker Origin[3]; and (ii) make several non-substantive formatting changes to the Exchange Rebates/Fees tables in Section 1(a)(i) of the Fee Schedule.

Background

The Exchange currently assesses transaction rebates and fees to all market participants, which are based upon a threshold tier structure (''Tier''). Tiers are determined on a monthly basis and are based on three alternative calculation methods, as defined in Section 1(a)(ii) of the Fee Schedule. The calculation method that results in the highest Tier achieved by the Member[4] shall apply to all Origin types by the Member, except the Priority Customer[5] Origin type (calculation of Tiers discussed below). The monthly volume thresholds for each method, associated with each Tier, are calculated as the total monthly volume executed by the Member in all options classes on MIAX Emerald in the relevant Origins and/or applicable liquidity, not including Excluded Contracts,[6] (as the numerator) expressed as a percentage of (divided by) Customer Total Consolidated Volume (''CTCV'') (as the denominator). CTCV is calculated as the total national volume cleared at The Options Clearing Corporation (''OCC'') in the Customer range in those classes listed on MIAX Emerald for the month for which fees apply, excluding volume cleared at the OCC in the Customer range executed during the period of time in which the Exchange experiences an ''Exchange System Disruption''[7] (solely in the option classes of the affected Matching Engine).[8] In addition, the per contract transaction rebates and fees shall be applied retroactively to all eligible volume once the Tier has been reached by the Member. Members that place resting liquidity, *i.e.,* orders on the MIAX Emerald System, will be assessed the specified ''maker'' rebate or fee (each a ''Maker'') and Members that execute against resting liquidity will be assessed the specified ''taker'' fee or rebate (each a ''Taker'').[9] Members are also assessed lower transaction fees and smaller rebates for order executions in standard option classes in the Penny Interval Program[10] (''Penny classes'') than for order executions in standard option classes which are not in the Penny Program (''non-Penny classes''), for which Members will be assessed a higher transaction fees and larger rebates.

For the Priority Customer Origin type, the Tier applied for a Member and its Affiliates'[11] is solely determined by

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Market Maker'' refers to ''Lead Market Maker'' (''LMM''), ''Primary Lead Market Maker'' (''PLMM'') and ''Registered Market Maker'' (''RMM''), collectively. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[4] ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[5] ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Exchange Rule 100, including Interpretation and Policy .01.

[6] ''Excluded Contracts'' means any contracts routed to an away market for execution. *See* the Definitions Section of the Fee Schedule.

[7] The term ''Exchange System Disruption'' means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hour or more, during trading hours. *See* the Definitions Section of the Fee Schedule.

[8] A ''Matching Engine'' is a part of the MIAX Emerald electronic system that processes options orders and trades on a symbol-by-symbol basis. *See* the Definitions Section of the Fee Schedule.

[9] For a Priority Customer complex order taking liquidity in both a Penny class and non-Penny class against Origins other than Priority Customer, the Priority Customer order will receive a rebate based on the Tier achieved.

[10] *See* Securities Exchange Act Release No. 88993 (June 2, 2020), 85 FR 35145 (June 8, 2020) (SR–EMERALD–2020–05) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 510, Minimum Price Variations and Minimum Trading Increments, To Conform the Rule to Section 3.1 of the Plan for the Purpose of Developing and Implementing Procedures Designed To Facilitate the Listing and Trading of Standardized Options) (the ''Penny Program'').

[11] ''Affiliate'' means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An ''Appointed Market Maker'' is a MIAX Emerald Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an ''Appointed EEM'' is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Emerald Market Maker) that has been appointed by a MIAX Emerald Market Maker, pursuant to the following process. A MIAX Emerald Market Maker appoints an EEM and an EEM appoints a MIAX Emerald Market Maker, for the purposes of the Fee Schedule, by each completing and sending an

calculation Method 3, as defined in Section 1(a)(ii) of the Fee Schedule, titled ''Total Priority Customer, Maker sides volume, based on % of CTCV ('Method 3').''

Decrease to Simple Maker Rebates in Certain Tiers for Options in Penny Classes for the Market Maker Origin

The Exchange proposes to amend Section 1(a)(i) of the Fee Schedule to decrease certain Simple Maker rebates in Tiers 1 and 2 for options in Penny Classes for the Market Maker Origin. Currently, the Exchange provides a Simple Maker rebate of ($0.35) for Members that achieve Tiers 1 and 2 for options transactions in Penny Classes for the Market Maker Origin. The Exchange now proposes to decrease these rebates. In particular, the Exchange proposes to provide Simple Maker rebates of ($0.30) and ($0.33) for Members that achieve Tiers 1 and 2, respectively, for options transactions in Penny Classes for the Market Maker Origin.

The purpose of adjusting the specified Simple Maker rebates is for business and competitive reasons. In order to attract order flow, the Exchange initially set its Maker rebates so that they were meaningfully higher than other options exchanges that operate comparable maker/taker pricing models.[12] The Exchange now believes that it is appropriate to adjust these specified Maker rebates so that they are more in line with other exchanges, but will still remain highly competitive such that they should enable the Exchange to continue to attract order flow and maintain market share.[13]

Formatting Changes to Tables of Exchange Rebates/Fees

Next, the Exchange proposes to amend tables in Section 1(a)(i) of the Fee Schedule for the Exchange's rebates and fees for Penny Classes and non-Penny Classes to make non-substantive formatting changes to several Tiers for the Priority Customer Origin. The Exchange proposes to amend the Complex[14] Maker rebates in Tiers 1–4 for the Priority Customer Origin when contra to Priority Customer Origin for Penny and non-Penny Classes to align the rebates with footnote ''*''. When the Exchange established the initial Fee Schedule, it adopted footnote ''*'', which provides as follows: ''Priority Customer Complex Orders contra to Priority Customer Complex Orders are neither charged nor rebated. Priority Customer Complex Orders that leg into the Simple book are neither charged nor rebated.''[15] Accordingly, the Exchange proposes to amend the Complex Maker rebates in Tiers 1–4 for the Priority Customer Origin when contra to Priority Customer Origin for Penny and non-Penny Classes so that all these rebates will be listed in the tables as ''($0.00)'' to align with footnote ''*''. The purpose of these proposed changes is to reconcile Complex Maker rebates for the Priority Customer Origin in Tiers 1–4 when contra to Priority Customer Origin with footnote ''*'' to eliminate potential confusion between the tables and the footnotes below the tables. The Exchange notes that these proposed changes will have no impact on the application of the tiers to the Priority Customer Origin or the footnote ''*''.

Implementation

The proposed changes are scheduled to become operative January 1, 2022.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[16] in general, and furthers the objectives of Section 6(b)(4) of the Act,[17] in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange members and issuers and other persons using its facilities, and 6(b)(5) of the Act,[18] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[19]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 15% market share.[20] Therefore, no exchange possesses significant pricing power. More specifically, as of December 13, 2021, the Exchange had a market share of approximately 5.03% of executed volume of multiply-listed equity and exchange traded fund (''ETF'') options for the month of December 2021.[21]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products and services, terminate an existing membership or determine to not become a new member, and/or shift order flow, in response to transaction fee changes. For example, on February 28, 2019, the Exchange's affiliate, MIAX PEARL, LLC (''MIAX Pearl'') filed with the Commission a proposal to increase Taker fees in certain Tiers for options transactions in certain Penny classes for Priority Customers and decrease Maker rebates in certain Tiers for options transactions in Penny classes for Priority Customers (which fee was to be effective March 1, 2019).[22] MIAX Pearl experienced a decrease in total market share for the month of March 2019, after the proposal

executed Volume Aggregation Request Form by email to *membership@miaxoptions.com* no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange's acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. *See* the Definitions Section of the MIAX Emerald Fee Schedule.

[12] *See* Securities Exchange Act Release No. 85393 (March 21, 2019), 84 FR 11599 (March 27, 2019) (SR–EMERALD–2019–15).

[13] *See* NYSE Arca Options Fees and Charges, Market Maker Penny and SPY Posting Credit Tiers, page 10 (''Base'' tier rebate of ($0.28) and ''Select Tier'' rebate of ($0.32)); Cboe BZX Options Exchange Fee Schedule, Transaction Fees, Market Maker (base tier rebate of ($0.29) and tier rebate of ($0.33)).

[14] *See* Exchange Rule 518(a)(5) for the definition of a Complex Order.

[15] *See supra* note 12.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78f(b)(1) and (b)(5).

[19] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[20] *See* ''The Market at a Glance,'' (last visited December 13, 2021), available at *https://www.miaxoptions.com/*.

[21] *See id*.

[22] *See* Securities Exchange Act Release No. 85304 (March 13, 2019), 84 FR 10144 (March 19, 2019) (SR–PEARL–2019–07).

went into effect. Accordingly, the Exchange believes that the MIAX Pearl March 1, 2019 fee change, to increase certain transaction fees and decrease certain transaction rebates, may have contributed to the decrease in MIAX Pearl's market share and, as such, the Exchange believes competitive forces constrain the Exchange's, and other options exchanges, ability to set transaction fees and market participants can shift order flow based on fee changes instituted by the exchanges.

The Exchange believes its proposal to decrease Simple Maker rebates in certain Tiers for options transactions in Penny Classes for Market Makers is reasonable, equitable and not unfairly discriminatory because all similarly situated market participants in the same Origin type are subject to the same tiered Maker rebates and access to the Exchange is offered on terms that are not unfairly discriminatory. The Exchange believes it is equitable and not unfairly discriminatory to reduce the Simple Maker rebates for Market Maker quotes or orders in Penny Classes for business and competitive business reasons. The Exchange initially set its Simple Maker rebates for such orders higher than certain other options exchanges that operate comparable maker/taker pricing models. The Exchange now believes that it is appropriate to further decrease those specified Simple Maker rebates so that they are more in line with other exchanges, and will still remain highly competitive such that they should enable the Exchange to continue to attract order flow and maintain market share.[23] The Exchange believes that the amount of such rebates, as proposed, will continue to encourage those market participants to send quotes or orders to the Exchange.

The Exchange believes the proposed formatting changes are consistent with Section 6(b)(4) of the Act in that they are reasonable, equitable, and not unfairly discriminatory because they are non-substantive, clarifying changes regarding the Exchange's Complex Maker rebates in Tiers 1–4 for the Priority Customer Origin when contra to Priority Customer Origin for Penny and non-Penny Classes. The Exchange believes that the proposed formatting changes will reduce the risk of confusion to market participants. The proposed changes promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general protect investors and the public interest by reconciling the Complex Maker rebates listed in Tiers 1–4 for the Priority Customer Origin when contra to Priority Customer Origin for Penny and non-Penny Classes and the description of the rebates for that type of transaction in footnote ''*'', below the tables. The Exchange believes that these proposed changes will provide greater clarity to Members and the public regarding the Exchange's Fee Schedule and that it is in the public interest for the Fee Schedule to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange believes that the proposed changes in the specified Simple Maker rebates for the applicable market participants should continue to encourage the provision of liquidity that enhances the quality of the Exchange's market and increases the number of trading opportunities on the Exchange for all participants who will be able to compete for such opportunities. The proposed rule changes should enable the Exchange to continue to attract and compete for order flow with other exchanges. However, this competition does not create an undue burden on competition but rather offers all market participants the opportunity to receive the benefit of competitive pricing.

Inter-Market Competition

The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has exceeded approximately 15% of the market share of executed volume of multiply-listed equity and ETF options trades as of December 13, 2021, for the month of December 2021.[24] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, as of December 13, 2021, the Exchange had a market share of approximately 5.03% of executed volume of multiply-listed equity and ETF options for the month of December 2021.[25] In such an environment, the Exchange must continually adjust its transaction and non-transaction fees to remain competitive with other exchanges and to attract order flow. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's rebates in a manner that will allow the Exchange to remain competition for Market Maker volume. To the extent this is achieved, all the Exchange's market participants should benefit from the improved market quality.

Formatting Changes

The Exchange believes the proposed formatting changes will not impose any burden on intra-market competition as the proposed rule change will have no impact on competition as it is not designed to address any competitive issue but rather is designed to remedy minor non-substantive issues and provide added clarity to the Fee Schedule. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal does not address any competitive issues and is intended to protect investors by providing further transparency regarding the Exchange's Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[26] and Rule 19b–4(f)(2)[27] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[23] *See supra* note 13.

[24] *See supra* note 20.

[25] *See id.*

[26] 15 U.S.C. 78s(b)(3)(A)(ii).

[27] 17 CFR 240.19b–4(f)(2).

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–EMERALD–2021–45 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–EMERALD–2021–45. 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–EMERALD–2021–45, and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00880 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93958; File No. SR–CBOE–2021–068]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change To Adopt a Modified Trading Schedule for Holidays

January 12, 2022.

On November 15, 2021, Cboe Exchange, Inc. 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 adopt a modified trading schedule for holidays. The proposed rule change was published for comment in the **Federal Register** on December 3, 2021.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that, within 45 days of the publication of notice of the filing of a 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 January 17, 2022.

The Commission hereby is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates March 3, 2022, 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–CBOE–2021–068).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00872 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93677 (November 29, 2021), 86 FR 68703.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93955; File No. SR–CBOE–2021–076]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

January 12, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 30, 2021, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule in connection with certain surcharges, a trading floor-related fee and its Global Trading Hours (''GTH'') Cboe Volatility Index (''VIX'') options/VIX weekly (''VIXW'') options and S&P 500 Index (''SPX'') options/SPX weekly (''SPXW'') LMM Incentive Programs, effective January 2, 2022.

First, the Exchange proposes to amend the Execution Surcharge fee in Rate Table—Underlying Symbol List A of the Fees Schedule applicable to non-Market-Maker orders [3] executed electronically in SPXW options. Currently, a surcharge fee of $0.13 per contract is assessed for non-Market-Maker orders executed electronically in SPXW. The proposed rule change slightly increases this surcharge fee from $0.13 per contract to $0.14 per contract. The Exchange notes that the proposed SPXW Execution Surcharge fee is still less than the Execution Surcharge fee assessed for SPX and SPESG transactions.[4]

Next, the Exchange proposes to marginally increase the Index License Surcharge fees currently applicable to orders executed in SPX (including SPXW) options in Rate Table—Underlying Symbol List A and to orders executed in MSCI Emerging Markets Index (''MXEF'') options and MSCI EAFE Index (''MXEA'') options (collectively, ''MSCI options'') in Rate Table—All Products Excluding Underlying Symbol List A. Specifically, the Exchange currently assesses an Index License Surcharge fee of $0.17 per contract for non-Customer orders executed in SPX/SPXW and an Index License Surcharge fee of $0.10 per contract for non-Customer orders executed in MSCI options. The proposed rule change increases the Index License Surcharge fee applicable to orders executed in SPX/SPXW from $0.17 per contract to $0.18 per contract and the Index License Surcharge fee applicable to orders executed in MSCI options from $0.10 per contract to $0.12 per contract. The Exchange notes that the Index License Surcharge fees in place for SPX/SPXW and MSCI options are designed to recoup some of the costs associated with the licenses for these indexes.[5] The Exchange has recently renewed its license arrangements for its SPX and MSCI index licenses and, as a result, the proposed rule change amends the Index License Surcharge fees for SPX/SPXW and MSCI options in order to continue to offset some of the costs associated with the licenses for these indexes.

Next, the Exchange proposes to amend a badge type in the Access Badges table of the Fees Schedule. Currently, a $70.00 fee is assessed for Clerk badges to access the Exchange's trading floor. The Exchange proposes to extend this badge fee to clerks and other Trading Permit Hold (''TPH'') employees in order to cover TPH employees that also receive an access badge to the Exchange's trading floor (*e.g.,* TPH technical support personnel). The Exchange notes that badge access is optional and other TPH employees may continue to be admitted to the trading floor if signed in by authorized TPH personnel.

Finally, the Exchange proposes to amend the rebates provided under its GTH1 and GTH2 VIX/VIXW LMM Incentive Programs and amend certain quote width categories under its GTH2 SPX/SPXW LMM Incentive Program. In particular, the Exchange offers, among other LMM incentive programs, a GTH1 VIX/VIXW LMM Incentive Program that applies during GTH from 7:15 p.m. CST to 2:00 a.m. CST (''GTH1'') and a GTH2 VIX/VIXW LMM Incentive Program and GTH2 SPX/SPXW LMM Incentive Program that apply during GTH from 2:00 a.m. CST to 8:15 a.m. CST (''GTH2''). The Exchange notes that these LMM incentive programs in the Fees Schedule provide a rebate to TPHs with LMM appointments to the respective incentive program that meet certain quoting standards in VIX/VIXW and SPX/SPXW, as applicable, in a month. The Exchange notes that meeting or exceeding the quoting standards in VIX/VIXW or SPX/SPXW to receive the applicable rebates (as currently offered and as proposed; described in further detail below) is optional for an LMM appointed to one of the GTH VIX/VIXW and SPX/SPXW LMM Incentive Programs. Rather, an LMM appointed to an incentive program is eligible to receive the corresponding rebate if it satisfies the applicable quoting standards (as currently offered and as proposed, described in further detail below), which the Exchange believes encourages an LMM to provide liquidity in the applicable program's products during GTH. The Exchange may consider other exceptions to the programs' quoting standards based on demonstrated legal or regulatory requirements or other mitigating circumstances. In calculating whether an LMM appointed to a GTH VIX/VIXW or GTH2 SPX/SPXW incentive program meets the applicable program's quoting standards each month, the Exchange excludes from the calculation in that month the business day in which the LMM missed meeting or exceeding the quoting standards in the highest number of series.

An LMM appointed to one of the GTH VIX/VIXW LMM Incentive Programs must provide continuous electronic quotes during GTH1 or GTH2, as applicable, that meet or exceed the quoting standards under the applicable program in at least 99% of each of the VIX and VIXW series, 90% of the time in a given month in order to receive a rebate for that month in the amount of $15,000 for VIX and $10,000 for VIXW (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month) for that month. The Exchange now proposes to increase each rebate amount received under the GTH1 and GTH2 VIX/VIXW LMM Incentive Programs for meeting the applicable quoting standards in a given month in VIX and VIXW, by slightly increasing the rebate amount for VIX from $15,000 to $20,000 and in VIXW, by slightly increasing the rebate amount from $10,000 to $15,000. The Exchange notes that no changes are being made to the quoting standards under the GTH1 or GTH2 VIX/VIXW LMM Incentive Programs. The Exchange wishes to

[3] Non-Market-Makers include Customers (capacity ''C''), Clearing Trading Permit Holders (capacity ''F''), Non-Clearing Trading Permit Holder Affiliates (capacity ''L''), Broker-Dealers (capacity ''B''), Joint Back-Offices (capacity ''J''), Non-Trading Permit Holder Market-Makers (capacity ''N''), and Professionals (capacity ''U''). Capacity ''M'' applies to Market-Makers.

[4] *See* Cboe Options Fees Schedule, Rate Table—Underlying Symbol List A, Execution Surcharge, SPX (not including SPXW) and SPESG, which assesses a surcharge fee of $0.21 per contract for non-Market-Maker orders in SPX and SPESG.

[5] *See* Securities Exchange Release Nos. 74854 (April 30, 2015), 80 FR 26124 (May 6, 2015) (SR–CBOE–2015–041); and 74422 (March 4, 2015), 80 FR 12680 (March 10, 2015) (SR–CBOE–2015–020).

further incentivize the LMMs appointed to the GTH VIX/VIXW LMM Incentive Programs to provide significant liquidity in VIX/VIXW options during all of GTH by meeting the applicable quoting standards currently under each program in order to receive the proposed increased rebates.

An LMM appointed to the GTH2 SPX/SPXW LMM Incentive Program must provide continuous electronic quotes during GTH2 that meet or exceed the quoting standards, provided below, in at least 85% of each of the SPX and SPXW series, 90% of the time in a given month in order to receive a rebate for that month in the amount of $15,000 for SPX and $35,000 for SPXW (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month) for that month.

Premium level	Expiring		Near term		Mid term		Long term	
	7 days or less		8 days to 60 days		61 days to 270 days		271 days to 500 days	
	Width	Size	Width	Size	Width	Size	Width	Size
VIX Value at Prior Close <20								
$0.00–$5.00	$0.35	25	$0.40	15	$0.60	5	$1.20	5
$5.01–$15.00	0.60	20	0.60	20	1.50	10	2.00	5
$15.01–$50.00	1.20	15	2.00	15	2.00	10	4.00	5
$50.01–$100.00	6.00	10	4.00	10	3.00	10	5.00	5
$100.01–$200.00	15.00	1	5.00	5	4.00	5	6.00	5
Greater than $200.00	20.00	1	8.00	1	12.00	1	50.00	1
VIX Value at Prior Close from 20–30								
$0.00–$5.00	0.60	15	0.80	10	0.75	5	2.00	5
$5.01–$15.00	1.00	15	1.00	15	2.20	5	3.00	5
$15.01–$50.00	2.50	10	3.50	10	3.0	5	5.00	5
$50.01–$100.00	10.00	10	7.00	10	3.50	5	7.00	5
$100.01–$200.00	18.00	1	8.00	5	6.00	5	10.00	5
Greater than $200.00	25.00	1	12.00	1	2.00	1	60.00	1
VIX Value at Prior Close >30								
$0.00–$5.00	0.90	10	1.00	10	1.00	5	3.00	5
$5.01–$15.00	2.50	10	2.50	10	3.00	5	4.00	5
$15.01–$50.00	4.00	10	5.00	10	5.00	5	8.00	5
$50.01–$100.00	12.00	5	10.00	5	4.50	3	10.00	1
$100.01–$200.00	20.00	1	12.00	5	15.00	1	18.00	1
Greater than 200.00	30.00	1	25.00	1	30.00	1	70.00	1

The Exchange proposes to marginally widen certain quotes widths applicable when the VIX Index value at the prior close is less than 20 for SPX/SPXW options expiring in 7 days or less as follows: Widen the quote width that corresponds to the $5.01 to $15.00 premium level from $0.60 to $0.80; widen the quote width that corresponds to a premium level of $15.01 to $50.00 from $1.20 to $1.80; and widen the quote width that corresponds to the premium level of $50.01 to $100.00 from $6.00 to $7.50. The Exchange notes that, generally, demand for and participation in SPX/SPXW options decreases as time to expiration decreases and, as a result, it becomes more difficult for LMMs to quote within specified widths and sizes for SPX/SPXW options that expire in 7 days or less. As such, the proposed rule change is designed to slightly ease the quoting requirements under the expiration category of 7 days or less (when the VIX Index value is less than 20 at the prior close) by marginally widen certain quote widths in order to better enable and encourage LMMs to satisfy the quoting standards to receive the current monthly rebate applicable to SPX and/or SPXW.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[8] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes amending the Execution Surcharge fee applicable to non-Market-Maker electronic orders in SPXW is reasonable as such fee is still lower than the Execution Surcharge fee applicable to non-Market-Maker orders transacted in SPX and SPESG.[9] Additionally, the proposed increase helps to ensure that there is reasonable cost equivalence between the primary execution channels for SPXW. More specifically, the SPXW Surcharge fee was adopted to minimize the cost differentials between manual and electronic executions, which is in the interest of the Exchange as it must both maintain robust electronic systems as well as provide for economic opportunity for floor brokers to continue to conduct business, as they serve an important function in achieving price discovery and customer executions.[10] The Exchange believes the proposed change is also equitable and not unfairly

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78f(b)(4).

[9] *See supra* note 4.

[10] *See* Securities Exchange Act Release No. 71295 (January 14, 2014) 79 FR 3443 (January 21, 2014) (SR–CBOE–2013–129).

discriminatory as it will continue to apply uniformly to all non-Market-Maker orders executed electronically in SPXW.

The Exchange believes that it is reasonable to increase the amount of the Index License Surcharge fees for orders in SPX/SPXW and MSCI options as the proposed increases are consistent with the purpose of such surcharge fees as they are intended to continue to help recoup some of the costs associated with the license for such products in light of recently renewed license arrangements between the Exchange and the applicable index providers. The proposed Index License Surcharge fees are also equitable and not unfairly discriminatory because the surcharge fees will continue to be assessed uniformly for all non-Customer orders in SPX/SPXW and MSCI options, as applicable.

The Exchange believes the proposed rule change to extend the access badge fee to other TPH employees, in addition to clerks, is reasonable as it is designed to cover TPH employees that also receive an access badge to the Exchange's trading floor (*e.g.,* TPH technical support personnel). The Exchange again notes that badge access is optional and other TPH employees may continue to be admitted to the trading floor if signed in by TPH personnel with badge access. The extension of the access badge fee to other TPH employees is equitable and not unfairly discriminatory because it will apply uniformly to all TPH employees that opt to receive an access badge.

Regarding the GTH VIX/VIXW LMM Incentive Programs and the GTH2 SPX/SPXW LMM Incentive Program, generally, the Exchange believes it is reasonable, equitable and not unfairly discriminatory to continue to offer these financial incentives, including as amended, to LMMs appointed to the programs, because it benefits all market participants trading in the corresponding products during GTH. These incentive programs encourage the LMMs appointed to such programs to satisfy the applicable quoting standards, which may increase liquidity and provide more trading opportunities and tighter spreads. Indeed, the Exchange notes that these LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade VIX/VIXW and SPX/SPXW options, as applicable, which can lead to increased volume, providing for robust markets. The Exchange ultimately offers the LMM Incentive Programs, as amended, to sufficiently incentivize LMMs appointed to each incentive program to provide key liquidity and active markets in the corresponding program products during the corresponding trading sessions. The Exchange believes that these incentive programs, as amended, will continue to encourage increased quoting to add liquidity in each of the corresponding program products, thereby protecting investors and the public interest. The Exchange also notes that an LMM appointed to an incentive program may undertake added costs each month to satisfy that heightened quoting standards (*e.g.,* having to purchase additional logical connectivity).

In particular, the Exchange believes that the proposed increases to the rebates applicable to VIX and VIXW provided under the GTH VIX/VIXW LMM Incentive programs are reasonably designed to continue to incentivize an appointed LMM to meet the applicable quoting standards for VIX/VIXW options during GTH, thereby providing liquid and active markets, which facilitates tighter spreads, increased trading opportunities, and overall enhanced market quality to the benefit of all market participants. The Exchange further believes that the proposed rule change to amend the rebate amount received for VIX ($20,000) and VIXW options ($15,000) is reasonable because it is comparable to and within the range of the rebates offered by other LMM Incentive Programs. For example, the GTH SPX/SPXW LMM Programs currently offers $15,000 for SPX and $35,000 SPXW options in which the applicable quoting standards are met in a given month. The Exchange believes the proposed rebates applicable to the GTH VIX/VIXW LMM Incentive Programs are equitable and not unfairly discriminatory because they will continue to apply equally to any TPH that is appointed as an LMM to the GTH1 and GTH2 VIX/VIXW LMM Incentive Programs.

The Exchange believes that it is reasonable to slightly ease the quoting requirements under the GTH2 SPX/SPXW LMM Incentive Program by marginally widen certain quote widths for SPX/SPXW options that expire in 7 days or less, wherein it becomes more difficult for LMMs to quote within specified widths, in order to better enable and encourage LMMs to satisfy the quoting standards to receive the current monthly rebate applicable to SPX and/or SPXW. As such, the Exchange believes the slightly wider quote widths are reasonably designed to facilitate LMMs appointed to the GTH2 SPX/SPXW LMM Incentive Program in meeting the heightened quoting standards (in order to receive the current rebate offered under the program) by increasing their quoting activity and posting tighter spreads and more aggressive quotes in SPX/SPXW options during GTH2. An increase in quoting activity and tighter quotes tends to signal additional corresponding increase in order flow from other market participants, which benefits all investors by deepening the Exchange's liquidity pool, potentially providing even greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. The Exchange also believes that the proposed widths are reasonable because they remain generally aligned with the current heightened quoting standards in the program, as the proposed widths are only marginally larger than the current widths. The Exchange believes that the proposed increase in certain quote widths under the GTH2 SPX/SPXW LMM Incentive Program is equitable and not unfairly discriminatory because such quote widths will continue to apply equally to any and all TPHs with LMM appointments to the GTH2 SPX/SPXW LMM Incentive Program that seek to meet the program's heightened quoting standards in order to receive the current rebates offered under the program.

Additionally, the Exchange notes if an LMM appointed to the GTH VIX/VIXW LMM Incentive Programs or the GTH2 SPX/SPXW LMM Incentive Program does not satisfy the corresponding quoting standards for any given month, then it simply will not receive the rebate(s) offered by the respective program for that month.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule changes in connection with surcharge fees will impose any burden on intramarket competition because each applies uniformly to all similarly situated TPHs in a uniform manner (*i.e.,* to all non-Market-Maker electronic executions in SPXW and to all non-Customer executions in SPX/SPXW or MSCI options). Additionally, the access badge fee will apply uniformly to all other TPH employees in the same manner as it applies to all clerk badges today. The Exchange again notes that badge access is optional and

other TPH employees may continue to be admitted to the trading floor if signed in by TPH personnel with badge access. Additionally, the proposed changes to existing GTH VIX/VIXW and SPX/SPXW LMM Incentive Programs will apply to all LMMs appointed to the applicable program classes (*i.e.,* VIX/VIXW and SPX/SPXW) in a uniform manner. To the extent these LMMs appointed to an incentive program receive a benefit that other market participants do not, as stated, these LMMs in their role as Mark-Makers on the Exchange have different obligations and are held to different standards. For example, Market-Makers play a crucial role in providing active and liquid markets in their appointed products, thereby providing a robust market which benefits all market participants. Such Market-Makers also have obligations and regulatory requirements that other participants do not have. The Exchange also notes that an LMM appointed to an incentive program may undertake added costs each month that it needs to satisfy that heightened quoting standards (*e.g.,* having to purchase additional logical connectivity). The Exchange also notes that the incentive programs are designed to attract additional order flow to the Exchange, wherein greater liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity.

The Exchange does not believe that the proposed rule changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed amendments to the surcharges and the LMM Incentive Programs, apply only to Exchange proprietary products, which are traded exclusively on Cboe Options. Additionally, the Exchange notes that at least one other options exchange assesses a badge fee for employees of on-floor registrants.[11]

Additionally, the Exchange notes that it operates in a highly competitive market. TPHs have numerous alternative venues that they may participate on and direct their order flow, including 15 other options exchanges, as well as off-exchange venues, where competitive products are available for trading. Based on publicly available information, no single options exchange has more than 15% of the market share.[12] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange, and, additionally off-exchange venues, if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[14] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[11] *See* BOX FEE Schedule, Section VIII C, Trading Floor Participant Fees, which assesses a $100 badge fee for ''all other registered on-floor persons employed by or associated with a Floor Market Maker or Floor Broker''.

[12] *See* Cboe Global Markets U.S. Options Market Volume Summary, Month-to-Date (December 17, 2021), available at *https://www.cboe.com/us/options/market_statistics/.*

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2021–076 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–CBOE–2021–076. 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

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

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–CBOE–2021–076 and should be submitted on or before February 9, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00871 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: To be published.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, January 20, 2022 at 2 p.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Thursday, January 20, 2022 at 2 p.m. has been changed to Thursday, January 20, 2022 at 2:15 p.m.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: January 13, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–01000 Filed 1–14–22; 11:15 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93966; File No. SR–FINRA–2021–029]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving Proposed Rule Change To Amend FINRA Rule 6732 and Expand the Scope of Exemptions That FINRA May Grant ATSs From the TRACE Reporting Requirements

January 12, 2022.

I. Introduction

On November 15, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend FINRA Rule 6732 (Exemption from Trade Reporting Obligation for Certain Transactions on an Alternative Trading System) to expand the scope of exemptions from the transaction reporting obligations of FINRA Rule 6730 (Transaction Reporting) that FINRA may grant to a member alternative trading system (''ATS''). The proposed rule change was published for comment in the **Federal Register** on November 30, 2021.[3] The Commission received no comments on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposal

FINRA Rule 6730(a) requires each FINRA member that is a Party to a Transaction in a TRACE-Eligible Security [4] to report the transaction to the Trade Reporting and Compliance Engine (''TRACE''). FINRA Rule 6710(e) defines ''Party to a Transaction'' as an introducing broker-dealer (if any), an executing broker-dealer, or a customer. An alternative trading system (''ATS'') is a Party to a Transaction occurring through its system and has a TRACE transaction reporting obligation, unless an exception or exemption applies.[5]

FINRA Rule 6732 provides FINRA with the authority to exempt a member ATS from TRACE reporting obligations under FINRA Rule 6730. FINRA has stated that it adopted Rule 6732 in response to concerns raised by members regarding operational difficulties arising from the reporting of certain transactions on an ATS, particularly when the ATS does not have a role in the clearance and settlement for trades on its system.[6] If FINRA grants an ATS an exemption under Rule 6732, a member subscriber of the ATS, when engaging in a trade on the ATS covered by the Rule 6732 exemption, must report against its counterparty (rather than the ATS), which mitigates these operational difficulties and facilitates clearance and settlement.[7]

Currently, under Rule 6732, FINRA may grant an ATS an exemption if the following criteria are satisfied: (1) A trade is between two FINRA members; (2) the trade does not pass through any ATS account, and the ATS seeking the exemption does not exchange TRACE-Eligible Securities or funds on behalf of the subscribers or take either side of the trade for clearing or settlement purposes, or in any other way insert itself into the trade; (3) the ATS seeking the exemption agrees to provide data relating to each exempted trade to FINRA on either a monthly basis or as otherwise proscribed by FINRA, and acknowledges that failure to meet this requirement would result in its exemption being revoked; (4) the ATS seeking the exemption pays the applicable reporting fee to FINRA; and (5) the ATS seeking the exemption has entered into a written agreement with each member that is a Party to a Transaction to ensure that each exempted trade is properly reported.[8] Where these criteria are satisfied, an exempted trade occurring on the ATS must be reported by a member (other than the ATS) that meets the definition of ''Party to a Transaction'' identifying a counterparty other than the ATS with respect to each side of the trade.[9]

FINRA is now proposing to amend Rule 6732 to expand the scope of transactions that may be exempted under Rule 6732 to include trades that involve only one FINRA member (other than the ATS). Specifically, FINRA proposes to delete the current language in subparagraph (a)(1) of Rule 6732 that requires an exempted transaction to be between two FINRA members, and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93651 (November 23, 2021), 86 FR 67996 (November 30, 2021) (''Notice'').

[4] *See* FINRA Rule 6710(a) (defining ''TRACE-Eligible Security'').

[5] *See Regulatory Notice* 14–53 (November 2014).

[6] *See* Notice, 86 FR at 67997. FINRA explained that members' back-end systems are often programmed to clear against the counterparty identified on TRACE trade reports, and when the ATS is not involved in clearance and settlement, member subscribers often prefer to TRACE-report against the party with which they clear and settle the trade (*i.e.,* another subscriber, rather than the ATS). *See id.*

[7] *See id.*

[8] *See* FINRA Rule 6732(a).

[9] *See* FINRA Rule 6732(b).

replace it with the following: ''The trade involves at least one member (other than the ATS) that meets the definition of 'Party to a Transaction.' ''

FINRA has stated that, in many cases, transactions on an ATS that involve only one member are otherwise similar to the transactions between two members that are currently eligible for exemptive relief under existing Rule 6732.[10] FINRA believes that expanding the scope of the current exemption to permit its use for transactions between a member (other than the ATS) and a non-member subscriber would extend the benefits of the rule—including simplifying compliance with TRACE trade reporting obligations—for additional ATS models and member subscribers, while capturing substantially the same regulatory information and enabling public dissemination of the transaction in a more streamlined manner.[11]

FINRA also has proposed to add new paragraph (c) to Rule 6732, which provides that, with respect to a transaction between a member and a non-member on an ATS that is a ''covered ATS,''[12] the ATS must provide to the member subscriber, and the member subscriber must report to TRACE using, the FINRA-assigned identifier for each non-FINRA member subscriber. FINRA also has stated that an ATS that has received an exemption under Rule 6732 and that is a ''covered ATS'' must use the FINRA-assigned identifier to identify each non-FINRA member subscriber in the monthly transaction files that are required to be submitted to FINRA.[13]

FINRA has represented that it will announce the effective date of the rule change in a *Regulatory Notice,* and the effective date will be no later than 365 days following Commission approval of the proposed rule change.[14]

III. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act,[16] which requires, among other things, that the rules of a national securities association be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

The proposed rule change appears reasonably designed to reduce reporting burdens on member ATSs and to mitigate operational burdens of ATS member subscribers with respect to clearance and settlement, without negatively impacting the regulatory audit trail or post-trade transparency for ATS transactions in TRACE-Eligible Securities. The proposed rule change will expand the scope of existing Rule 6732 by allowing FINRA to grant exemptions from the TRACE reporting requirements to ATSs regarding member-to-non-member trades in addition to, as currently, member-to-member trades. The proposal does not change any of the other criteria for granting an exemption under Rule 6732.

Thus, although an ATS receiving an exemption pursuant to FINRA's expanded authority under Rule 6732 would no longer be submitting TRACE reports regarding exempted trades, the proposal appears reasonably designed to prevent any relevant information regarding such trades from being lost from the regulatory audit trail. An ATS granted an exemption under FINRA's expanded authority would have to enter into a written agreement with each member subscriber that is a Party to a Transaction that is exempted, specifying that the member must report that transaction to TRACE and identify the transaction as having occurred on the ATS using the ATS's MPID.[17] The sole member subscriber involved in the transaction would have to identify a counterparty other than the ATS with respect to each side of the transaction.[18] In addition, an ATS granted an exemption would have to agree to provide FINRA on a monthly basis (or such other basis as prescribed by FINRA) data relating to exempted trades occurring on the ATS's system, and to acknowledge that failure to report such data to FINRA, in addition to constituting a violation of FINRA rules, would result in revocation of any exemption granted pursuant to Rule 6732.[19] Furthermore, under new Rule 6732(c), for an exempted trade between a member and a non-member on an ATS that is a ''covered ATS'' under FINRA Rule 6730.07, the ATS would have to provide to the member subscriber (and the member subscriber would have to report to TRACE using) the FINRA-assigned identifier for each non-FINRA member subscriber.

The proposal also appears reasonably designed to prevent any negative impact on post-trade transparency. Although trade reports for exempt trades will no longer be submitted by the ATS and publicly disseminated, market observers will still have relevant information about the ATS trade between the member subscriber and the non-member because FINRA will continue to publicly disseminate the trade report submitted by the member subscriber that is the Party to the Transaction. This approach aligns public dissemination more closely with the legal and economic effects of the transaction, because an exemption under Rule 6732 can apply to a trade on the ATS only if the broker-dealer operator of the ATS is not a legal counterparty to the trade.[20]

For the reasons noted above, the Commission finds that the proposed rule change is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[21] that the proposed rule change (SR–FINRA–2021–029) is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–00879 Filed 1–18–22; 8:45 am]

BILLING CODE 8011–01–P

[10] *See* Notice, 86 FR at 67997.

[11] *See id.*

[12] *See* FINRA Rule 6730.07 (defining ''covered ATS'' as an ATS ''that executed transactions in U.S. Treasury Securities against non-FINRA member subscribers of $10 billion or more in monthly par value, computed by aggregating buy and sell transactions, for any two months in the preceding calendar quarter'').

[13] *See* Notice, 86 FR at 67998, n. 12.

[14] *See* Notice, 86 FR at 67998.

[15] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78o–3(b)(6).

[17] *See* FINRA Rule 6732(a)(5).

[18] *See* FINRA Rule 6732(b).

[19] *See* FINRA Rule 6732(a)(3).

[20] *See* FINRA Rule 6732(a)(2).

[21] 15 U.S.C. 78s(b)(2).

[22] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17305 and #17306; MISSOURI Disaster Number MO–00112]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Missouri

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for

the State of Missouri (FEMA–4636–DR), dated 01/10/2022.

Incident: Severe Storms, Straight-line Winds, and Tornadoes.

Incident Period: 12/10/2021.

DATES: Issued on 01/10/2022.

Physical Loan Application Deadline Date: 03/11/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 10/11/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/10/2022, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Bollinger, Dunklin, Iron, Madison, Pemiscot, Reynolds, Wayne

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17305 C and for economic injury is 17306 0.

(Catalog of Federal Domestic Assistance Number 59008)

Barbara E. Carson,

Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 2022–00895 Filed 1–18–22; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11629]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: Exhibition of ''Going to the Market, Early Morning'' Painting by Thomas Gainsborough

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary exhibition or display at The J. Paul Getty Museum at the Getty Center, Los Angeles, California, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–00905 Filed 1–18–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11630]

Private Sector Participation in Domestic and International Events on Spaceflight Safety, Sustainability, and Emerging Markets in Outer Space

ACTION: Notice of a meeting.

SUMMARY: The U.S. Department of State seeks private sector participation in a series of domestic and international events promoting space commerce as well as implementation of best practices for the peaceful uses of outer space for civil and commercial activities in a safe and responsible manner. These events and the participation of the commercial space sector, academia and other non-governmental organizations will assist the Department of State in fulfilling its responsibilities pursuant to the 2020 National Space Policy and the 2021 United States Space Priorities Framework.

DATES: Participants will serve as private sector advisors to U.S. delegations to one or more workshops, meetings, symposia, and other international events related to safety, sustainability, and emerging markets in outer space between the publication date of this Notice and December 31, 2022.

ADDRESSES: Attendance information, including addresses, will be posted on *https://www.state.gov/remarks-and-releases-bureau-of-oceans-and-international-environmental-and-scientific-affairs/.*

FOR FURTHER INFORMATION CONTACT: Ryan Guglietta, Foreign Affairs Officer, Office of Space Affairs, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, Washington, DC 20522, phone 860–573–0708, or email *gugliettart@state.gov.*

SUPPLEMENTARY INFORMATION: Events will vary in location and format, to include fully online, hybrid, and in-person activities. Short notice modification of plans may be required in response to pandemic precautions. Meetings may be stand alone or on the margins of related events, which may include, but are not limited to, the United Nations Committee on the Peaceful Uses of Outer Space (COPUOS) Scientific and Technical Subcommittee (STSC) in Vienna in February 2022, the COPUOS Legal Subcommittee (LSC) in Vienna in April 2022, the COPUOS plenary in Vienna in June 2022, and World Space Forums organized by the UN Office of Outer Space Affairs. There may also be additional opportunities to provide input on domestic policies and U.S. positions in other international diplomatic fora.

Participants should focus on the following:

Safety: Identify key safety issues for crewed and/or uncrewed outer space operations. Discuss current attempts to address these issues and suggest new concerns that may develop as private

sector space activities advance and evolve.

Sustainability: Explore efforts to promote responsible behavior in space. Examine best practices and guidelines aimed at preserving the outer space environment for future space investment, exploration and use. In particular, implementation of the 2019 COPUOS Long-Term Sustainability (LTS) guidelines and the multi-nation Artemis Accords should be considered.

Emerging Markets: Discuss the challenges to an economically viable space industry and how these challenges relate to the domestic and international regulatory environment. Share recent advances within the commercial space sector and how they may develop in the future. Evaluate how an expanding commercial sector may affect equities like terrestrial based astronomy, planetary protection, orbital debris mitigation, and other aspects of safe and sustainable operations in outer space.

Valda Vikmanis-Keller,

Director, Office of Space Affairs, Department of State.

[FR Doc. 2022–00866 Filed 1–18–22; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0017]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from 23 individuals for an exemption from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions would enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before February 18, 2022.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2021–0017 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/*, insert the docket number, FMCSA–2021–0017, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov*, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2021–0017), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/docket?D=FMCSA-2021-0017*. Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2021–0017, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

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

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The 23 individuals listed in this notice have requested an exemption from the hearing requirement in 49 CFR 391.41(b)(11). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding hearing found in

§ 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 3, 1971).

On February 1, 2013, FMCSA announced in a Notice of Final Disposition titled, ''Qualification of Drivers; Application for Exemptions; National Association of the Deaf,'' (78 FR 7479), its decision to grant requests from 40 individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers. Since that time the Agency has published additional notices granting requests from hard of hearing and deaf individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers.

III. Qualifications of Applicants

Yunier Alegre

Mr. Alegre, 33, holds a class E license in Florida.

Kenneth Alston

Mr. Alston, 33, holds a class D license in New Jersey.

Charles Armand

Mr. Armand, 39, holds a class A license in New Jersey.

Baldemar Barba

Mr. Barba, 24, holds a class C license in Texas.

Gary Barber

Mr. Barber, 70, holds a commercial driver's license in Wisconsin.

Desmond Dantzler

Mr. Dantzler, 51, holds a class D license in Arizona.

Jeremy Descloux

Mr. Descloux, 25, holds an operator's license in Washington.

Philip Fatigato

Mr. Fatigato, 28, holds a class D license in Illinois.

William Hoke

Mr. Hoke, 50, holds a class D license in New York.

Edward Larizza

Mr. Larizza, 24, holds a class C license in California.

Kevin Maddox

Mr. Maddox, 58, holds a class AM license in Georgia.

Bikien McKoy

Mr. McKoy, 48, holds a class A license in North Carolina.

Rage Muse

Mr. Muse, 33, holds a class A license in Minnesota.

Orlando Padilla

Mr. Padilla, 47, holds a class E license in Florida.

Michael Paul

Mr. Paul, 60, holds a class A license in Illinois.

Aaron Pitsker

Mr. Pitsker, 31, holds a class CM license in California.

Michael Principe

Mr. Principe, 33, holds a class C license in Texas.

William Rivas

Mr. Rivas, 31, holds a class C license in California.

Kenneth Salts

Mr. Salts, 45, holds a class D license in Ohio.

Issac Soto

Mr. Soto, 32, holds a class D license in Illinois.

Gary Sturdevant

Mr. Sturdevant, 43, holds a class CM license in Texas.

Richard Taulbee

Mr. Taulbee, 40, holds a class C license in Georgia.

Matthew Taylor

Mr. Taylor, 27, holds a class C license in Texas.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated under the **DATES** section of the notice.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–00904 Filed 1–18–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2022–0002]

National Transit Database Census Reporting Clarifications

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

ACTION: Notice; Request for comments.

SUMMARY: This notice provides interested parties with the opportunity to comment on changes to the Federal Transit Administration's (FTA) National Transit Database (NTD) reporting requirements as they relate to Urbanized Areas (UZA). Each year, transit systems use data from the Census Bureau to update their basic information (B–10) form indicating what urbanized areas and rural areas they serve, and also to complete their Federal Funding Allocation (FFA–10) form distributing their service data across those urbanized and rural areas. The Census Bureau is expected to define new UZAs based on 2020 Census data in calendar year 2022. FTA proposes that for NTD Report Year 2021 (RY 2021), transit systems would be required to complete a B–10 and FFA–10 form based on the UZAs from the 2010 Census, as usual. If the Census Bureau releases new UZAs prior to October 1, 2022, then transit systems would be required to complete new B–10 and FFA–10 forms as an addendum to the annual report at that time.

DATES: Comments are requested by February 18, 2022. FTA will consider all comments received before the close of business on the comment closing date. To the extent practicable, FTA may also consider comments received after that date.

ADDRESSES: You may file comments identified by docket number FTA–2022–0002 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Send comments to Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Management Facility, U.S. Department of Transportation, at (202) 493–2251.

Instructions: You must include the agency name (Federal Transit Administration) and Docket Number (FTA–2022–0002) for this notice, at the beginning of your comments. If sent by mail, submit two copies of your comments.

Electronic Access and Filing: This document and all comments received may be viewed online through the Federal eRulemaking portal at *http://www.regulations.gov or at the street address listed above.* Electronic submission and retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days a year. Please follow the instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at *https://www.federalregister.gov.*

Privacy Act: Except as provided below, all comments received into the docket will be made public in their entirety. The comments will be searchable by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You should not include information in your comment that you do not want to be made public. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or at *https://www.transportation.gov/*privacy.

FOR FURTHER INFORMATION CONTACT: Thomas Coleman, National Transit Database Program Manager, FTA Office of Budget and Policy, (202) 366–5333, *thomas.coleman@dot.gov.*

SUPPLEMENTARY INFORMATION: The National Transit Database (NTD) is the Federal Transit Administration's (FTA's) primary database for statistics on the transit industry. Each year, transit systems use data from the Census Bureau to update their basic information (B–10) form indicating what urbanized areas and rural areas they serve, and also to complete their Federal Funding Allocation (FFA–10) form distributing their service data across those urbanized and rural areas. In implementing the 2010 Census, FTA required transit systems to complete only one FFA–10 form for the 2011 annual report (76 FR 30997). Transit systems were not required to complete an FFA–10 form based on the UZA definitions from the 2000 Census. Instead, transit systems filled out one FFA–10 form for their 2011 annual report during the summer of 2012, following the release of the 2010 Census UZA definitions in spring 2012.

In 2021, the Census Bureau announced that the new UZA definitions from the 2020 Census will not be released until summer 2022 or later. These UZA definitions are necessary for the NTD to create apportionment files. Federal law requires FTA to use the most recent urbanized area definitions from the Census Bureau (49 U.S.C. 5302(23)) in formula funding apportionments.

For the 2021 annual report, NTD reporters have already begun completing an initial FFA–10 and B–10 forms using existing 2010 Census definitions. For Report Year 2021, FTA proposes to require transit systems to submit the B–10 and FFA–10 forms using 2010 Census data by the normal NTD annual report deadline. If the Census Bureau releases new urbanized area definitions prior to October 1, 2022, FTA would require transit operators to submit new B–10 and FFA–10 forms using 2020 Census data as an addendum to the annual report. Collecting this addendum based on 2020 Census data is necessary to allow FTA to meet the UZA definition found in 49 U.S.C. 5302(23) and produce apportionment data files that support the apportionment of formula funds. If the Census Bureau releases new urbanized area definitions on or after October 1, 2022, then FTA would not require the form addendum and would instead integrate the new urbanized area definitions into the 2022 reporting process.

To minimize reporting burden, transit operators will not have to fill in the addendum from scratch. The addendum will pull in as much data as possible from the initial FFA–10 and B–10 forms completed using 2010 Census UZA definitions, based on unchanged or minimally changed UZA boundaries.

Nuria I. Fernandez,

Administrator.

[FR Doc. 2022–00851 Filed 1–18–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0105; Notice 2]

BMW of North America, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: BMW of North America, LLC (BMW), a subsidiary of BMW AG, has determined that certain model year (MY) 2019 BMW F750 GS and F850 GS motorcycles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 205, *Glazing Materials.* BMW filed a noncompliance report dated October 19, 2018. BMW subsequently petitioned NHTSA on October 29, 2018, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces the grant of BMW's petition.

FOR FURTHER INFORMATION CONTACT: Leroy Angeles, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–5304, *Leroy.Angeles@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview

BMW has determined that certain MY 2019 BMW F750 GS and F850 GS motorcycles do not fully comply with paragraph S6.3 of FMVSS No. 205, *Glazing Materials* (49 CFR 571.205). BMW filed a noncompliance report dated October 19, 2018, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* BMW subsequently petitioned NHTSA on October 29, 2018, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Notice of receipt of BMW's petition was published with a 30-day public comment period, on February 27, 2020, in the **Federal Register** (85 FR 11447). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Then follow the online search instructions to

locate docket number ''NHTSA–2018–0105.''

II. Vehicles Involved

Approximately 604 MY 2019 BMW F750 GS and F850 GS motorcycles, manufactured between June 21, 2018, and September 19, 2018, are potentially involved.

III. Noncompliance

BMW explains that the noncompliance is that the subject motorcycles are equipped with windscreens that do not comply with paragraph S6.3 of FMVSS No. 205. Specifically, the subject windscreens were marked with the AS4 glazing type marking instead of the AS6 glazing type marking. The windscreens were AS6 glazing and should have been marked as the AS6 glazing type.

IV. Rule Requirements

Paragraph S6.3 of FMVSS No. 205 includes the requirements relevant to this petition. A manufacturer or distributor who cuts a section of glazing material to which this standard applies, for use in a motor vehicle or camper, must mark that material in accordance with section 7 of ANSI/SAE Z26.1–1996 and certify that its product complies with this standard in accordance with 49 U.S.C. 30115.

AS4 certified glazing is typically rigid plastic and is only permitted for use in certain locations. AS4 glazing may not be used for motorcycle windscreens. AS4 glazing is not subject to a flexibility test, whereas AS6 marked glazing is subject to this test. AS6 certified glazing is typically made of flexible plastic and, unlike AS4 certified glazing, can be used as a motorcycle windscreen. Additionally, AS6 certified glazing is not subject to two impact tests, an abrasion test, and a dimensional stability test, whereas, AS4 certified glazing is subject to these tests.

V. Summary of BMW's Petition

BMW described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety. The following views and arguments presented in this section ''V. Summary of BMW's Petition,'' are the views and arguments provided by BMW.

In support of its petition, BMW submitted the following reasoning:

1. FMVSS No. 205 Section 2 (Purpose) states, ''The purpose of this standard is to reduce injuries resulting from impact to glazing surfaces, to ensure a necessary degree of transparency in motor vehicle windows for driver visibility, and to minimize the possibility of occupants being thrown through the vehicle windows in collisions.''

2. Potentially affected vehicles conform to all of the FMVSS No. 205 performance requirements. Therefore, they satisfy the stated purpose of FMVSS No. 205 regarding a) injury reduction, and b) rider visibility.

3. Potentially affected vehicles conform to all the FMVSS No. 205 performance requirements. Therefore, there are no safety performance implications associated with this potential noncompliance.

4. BMW has not received any contacts from vehicle owners regarding this issue. Therefore, BMW is unaware of any vehicle owners that have encountered this issue.

5. BMW is unaware of any accidents or injuries that may have occurred as a result of this issue.

6. NHTSA has previously granted petitions for inconsequential noncompliance regarding FMVSS No. 205 involving marking of window glazing. BMW believes that its petition is similar to other manufacturers' petitions in which NHTSA has granted. Examples of similar petitions, in which NHTSA has granted, include the following:

- Ford Motor Company, 80 FR 11259 (March 2, 2015).
- Ford Motor Company, 78 FR 32531 (May 30, 2013).
- Ford Motor Company, 64 FR 70115 (December 15, 1999).
- General Motors, LLC, 79 FR 23402 (September 25, 2015).
- General Motors, LLC, 70 FR 49973 (August 25, 2005).
- Toyota Motor North America Inc., 68 FR 10307 (March 4, 2003).
- Fuji Heavy Industries USA, Inc., 78 FR 59088 (September 25, 2013).
- Mitsubishi Motors North America, Inc., 80 FR 72482 (August 22, 2015).
- Pilkington North America, Inc., 78 FR 22942 (April 17, 2003).
- Supreme Corporation, 81 FR 72850 (October 21, 2016).
- Custom Glass Solutions Upper Sandusky Corp., 80 FR 3737 (January 23, 2015).

7. Vehicle production has been corrected to conform to FMVSS No. 205 S6.

8. BMW also provided a copy of the FMVSS No. 205 Certification Report from AIB-Vincotte International N.V.

VI. NHTSA's Analysis

The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in a standard—as opposed to a *labeling requirement with no performance implications*—is more substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[1] Potential performance failures of safety-critical equipment are rarely deemed inconsequential.

An important issue to consider in determining inconsequentiality is the safety risk to individuals who experience the type of event against which the recall would otherwise protect.[2] In general, NHTSA does not consider the absence of complaints or injuries to show that the issue is inconsequential to safety. ''Most importantly, the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.'' [3] ''[T]he fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.'' [4]

NHTSA has evaluated the merits of BMW's petition for inconsequential noncompliance. The purpose of FMVSS No. 205 is to reduce injuries resulting from impact to glazing surfaces to ensure a necessary degree of transparency in motor vehicle windows for driver visibility, and to minimize the possibility of occupants being thrown through the vehicle windows in collisions.

The subject vehicles in BMW's petition have noncompliances that pertain to motorcycle windscreens that have incorrect AS markings. The Agency believes that it is important that the motorcycle windscreens equipped in the subject motorcycles are compliant with both FMVSS No. 205 performance

[1] *Cf. Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

[2] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[3] *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[4] *United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

and labeling requirements. Nonetheless, BMW's petition establishes that the incorrectly marked windscreens on the affected motorcycles conform to all FMVSS No. 205 performance requirements as evidenced in a test report showing the windscreens meet all the AS6 glazing performance requirements required by FMVSS No. 205.

As the performance requirements are met, NHTSA's principal concern is whether the noncompliant marking of the windscreen creates a safety risk in the event that consumers mistakenly believe the glazing meets the impact, abrasion, and dimensional stability requirements of AS4 glazing or attempt to replace the windscreen with AS4 glazing.

First, NHTSA considered whether the mismarking would lead a consumer to believe that the windscreen offers the same level of performance provided by AS4 glazing that is not provided by AS6 glazing material. Specifically, NHTSA considered whether a rider would believe that, as a result of the mismarking, the windscreen provides impact protection and meets dimensional stability and abrasion requirements. While this could be a potential safety risk, the size and placement of the subject windscreen was factored into NHTSA's analysis. The windscreens come in two sizes, one measuring 316 mm wide by 309 mm high, and the other measuring 314 mm wide by 216 mm high. The size, design, and placement of the subject windscreens appear such that a rider would expect that they would offer little to no impact protection. Further, the size and placement of the windscreens are such NHTSA does not believe that the mismarking will create a safety risk from riders believing that the windscreen meets the abrasion and dimensional stability requirements of AS4 glazing. According to BMW, the subject windscreens are intended to protect the dashboard electronics, deflect wind away from the rider, and serve as an aesthetic design for the motorcycle. Further, NHTSA believes that few riders know the differences in performance of AS4 and AS6 glazing. NHTSA believes that due to the size, design, placement of the subject windscreens, and the likelihood that riders would know the differences between the performance of AS4 and AS6 glazing, riders are unlikely to believe that the windscreen offers a higher level of performance than actually offered by the noncompliant windscreens.

Second, in the case that the windscreens require replacement, NHTSA believes that there is minimal risk in a motorcyclist being misled by the improper marking and concluding that a replacement windscreen must be of AS4 glazing rather than AS6 flexible glazing. The Agency believes that this risk is minimal because an AS4 replacement part would not be available and obtaining such a part would require that the new windscreen be custom fabricated from rigid AS4 glazing. If such fabrication were possible, it would likely entail considerable inconvenience and expense. Further, BMW or another replacement part supplier would be able to easily identify the correct AS6 replacement glazing through their replacement parts identification systems.

BMW's petition also cited multiple instances where NHTSA previously determined that incorrect AS markings on glazing were inconsequential for safety. The Agency first notes that use of previous determinations for inconsequential noncompliance should be viewed with caution as each inconsequential noncompliance petition is evaluated on the individual facts presented and determinations are made on a case-by-case basis. Further, of the eleven cited petitions, only 2 pertained to glazing that contained an incorrect AS glazing type marking and are potentially relevant to this petition. In both the petition from General Motors, LLC, (79 FR 23402, September 25, 2015) and the petition from Mitsubishi Motors North America, Inc. (80 FR 72482, August 22, 2015), AS3 glazing was marked as AS2 glazing. While the petitions are similar to BMW's, AS3 glazing and AS2 glazing have the same impact protection requirements. The analysis for this petition is different because, as discussed above, AS4 glazing is required to meet two impact tests that are not required for AS6 glazing.

Given that the windscreens in the subject motorcycles meet all the performance requirements as required by FMVSS No. 205 and the improper marking of the glazing presents no recognizable safety risk, the Agency finds that the subject glazing is inconsequential to motor vehicle safety.

VII. NHTSA's Decision

In consideration of the foregoing, NHTSA finds that BMW has met its burden of persuasion that the subject FMVSS No. 205 noncompliance in the affected vehicles is inconsequential to motor vehicle safety. Accordingly, BMW's petition is hereby granted. BMW is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject vehicles that BMW no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after BMW notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2022–00869 Filed 1–18–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Small Business Lending Fund Quarterly Supplemental Report

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on the proposed information collections listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before March 21, 2022.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, by the following method:

• *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number TREAS–DO–2022–0001 and the specific Office of Management and Budget (OMB) control number 1505–0228.

FOR FURTHER INFORMATION CONTACT: For questions related to these programs, please contact Steve Davidson by emailing *pra@treasury.gov,* or calling (202) 285–0346. Additionally, you can view the information collection requests at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Small Business Lending Fund Quarterly Supplemental Report.

OMB Control Number: 1505–0228.

Type of Review: Extension of a currently approved collection.

Description: Banks participating in the Small Business Lending Fund program are required to submit a Supplemental Report each quarter. The Supplemental Report is used to determine the bank's small business lending baseline and allows Treasury to assess the change in the small business lending for the previous quarter.

Forms: TD F 102.3A, TD F 102.4.

Affected Public: Businesses and other for-profits.

Estimated Number of Respondents: 56.

Frequency of Response: Quarterly.

Estimated Total Number of Annual Responses: 224.

Estimated Time per Response: 3.5 hours.

Estimated Total Annual Burden Hours: 784.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget 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 technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: January 12, 2022.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2022–00890 Filed 1–18–22; 8:45 am]

BILLING CODE 4810–AK–P

UNITED STATES INSTITUTE OF PEACE

Notice of Board of Directors Meeting

AGENCY: United States Institute of Peace (USIP) and Endowment of the United States Institute of Peace.

ACTION: Announcement of meeting.

SUMMARY: Meeting of the Board of Directors: Chair's Report; Vice Chair's Report; President's Report; Approval of Minutes; USIP Key Current Initiatives: *Ethiopia; Afghanistan and Pakistan; Strategic Stability;* and *Youth;* Reports from USIP Board Committees: Governance and Compliance; Strategy and Program; Audit and Finance; Security and Facilities; and Talent and Culture.

DATES: Friday, January 21, 2022 (10:00 a.m.–12:00 p.m.).

ADDRESSES: Virtual Board Meeting Information: Join by video: Join ZoomGov Meeting *https://usip-org.zoomgov.com/j/1617695522?pwd=dzMwNWFCbzJGZHlPOGZzUk15TjNBZz09;* Meeting ID: 161 769 5522; Passcode: 249160.

FOR FURTHER INFORMATION CONTACT: Megan O'Hare, 202–429–4144, *mohare@usip.org.*

SUPPLEMENTARY INFORMATION: Open Session—Portions may be closed pursuant to Subsection (c) of Section 552(b) of Title 5, United States Code, as provided in subsection 1706(h)(3) of the United States Institute of Peace Act, Public Law 98–525.

Authority: 22 U.S.C. 4605(h)(3).

Dated: January 10, 2022.

Megan O'Hare,

Chief of Staff.

[FR Doc. 2022–00921 Filed 1–18–22; 8:45 am]

BILLING CODE 6820–AR–P

FEDERAL REGISTER

Vol. 87 Wednesday,
No. 12 January 19, 2022

Part II

Department of Justice

Drug Enforcement Administration

Samson K. Orusa, M.D.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–26]

Samson K. Orusa, M.D.; Decision and Order

On May 31, 2019, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Samson K. Orusa (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed revocation of Respondent's DEA Certificate of Registration Number BO4959889 (hereinafter, registration or COR), the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations including the pending application for COR Number W18070589C pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's continued ''registrations are inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted on September 9, 2020, October 15, 2020, and October 21, 2020, via video teleconference technology. On December 8, 2020, Administrative Law Judge Mark M. Dowd, (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD) and neither party filed exceptions. I issue the final order in this case following the RD. Having reviewed the entire record, I adopt the ALJ's Recommended Decision with minor modifications, as noted herein.*[A]

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *[B]

The Drug Enforcement Administration (DEA) Assistant Administrator, filed an Order to Show Cause (OSC) [1] on May 31, 2019, the Certificate of Registration (COR), No. BO4959889, of Samson K. Orusa, M.D. (Respondent), proposing to revoke the Respondent's COR pursuant to 21 U.S.C. 824(a)(4) on the ground that the Respondent's registration is inconsistent with the public interest, as defined in 21 U.S.C. 823(f). [Omitted.] [2] [3] In its Supplemental Pre-hearing Statement (GSPHS), the Government further alleged that the Respondent made a material falsification in his renewal application of November 6, 2019, in violation of 21 U.S.C. 824(a)(1). ALJ Ex. 53, 54.[4] A hearing was conducted in this matter on September 9, 2020, October 15, 2020, and October 21, 2020, via video teleconference technology.[5]

The issue to be decided by the Administrator is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. BO4959889, issued to Respondent should be revoked, and any pending applications for modification or renewal of the existing registration should be denied, and any pending applications for additional registrations should be denied, because his continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4) and because he materially falsified his application under 21 U.S.C. 824(a)(1).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

Overview

1. The Respondent is registered with the DEA as a Practitioner authorized to handle controlled substances in Schedules II–V under DEA registration number BO4959889 at 261 Stonecrossing Drive, Clarksville, Tennessee 37042. His DEA COR BO4959889 expired by its terms on December 31, 2019.

2. On July 6, 2018, the Respondent submitted an application (Application Control No. Wl8070589C) to the DEA for a new DEA COR (the ''Application''). This application seeks a new DEA COR under his Kentucky medical license at 316 Pappy Drive, Oak Grove, Kentucky 42262.[6]

3. Presently, the Respondent is licensed in the State of Tennessee as a medical doctor with license number 28275. The Respondent's Tennessee medical license expires by its own terms on March 31, 2020. The Respondent is also licensed in the State of Kentucky as a physician with license number 33408. The Respondent's Kentucky medical license expires by its own terms on February 29, 2020.

4. As a licensed medical doctor in Tennessee, the Respondent is subject to TENN. CODE ANN. 63–6–6214(b)(12) through (14), as those provisions pertain to ''dispensing, prescribing, or otherwise distributing'' controlled substances. Specifically, section 63–6–214(b)(12) prohibits a physician from prescribing controlled substances ''not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition.'' Accordingly, section 63–6–214(b)(13) prohibits a physician from prescribing controlled substances to a person ''addicted to the habit of using controlled substances ''without'' making a bona fide effort to cure the [patient's] habit.'' To determine a violation of these provisions, the Tennessee Board of Medical Examiners uses a non-exhaustive list of guidelines (''the guidelines'') found in TENN. COMP. R. & REGS. 0880–02–.14(6)(e). The guidelines require that a physician (1) take a documented medical history; (2) conduct a physical examination; and (3) perform an adequate ''assessment and consideration of the [patient's] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.'' TENN. COMP. R. & REGS.

*[A] I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[B] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] ALJ Ex. 1.

[2] [Omitted.]

[3] [Omitted.]

[4] Allegations brought in the OSC and Government's Prehearing Statements provide sufficient notice to the Respondent to defend against. *Jose G. Zavaleta, M.D.,* 78 FR 27431, 27439 (2013) (Where the Government did not allege material falsification on the respondent's application in the Order to Show Cause, but did raise the issue in its Supplemental Pre-hearing Statement, the respondent was on notice that the issue would be considered at the hearing).

[5] Although in his Posthearing Brief, the Respondent suggests the hearing was ''truncated'', there was nothing abbreviated or shortened as to the proceeding, which is now over 18 months and counting, or as to the hearing. Neither party was limited as to their time for presentation or number of witnesses. The hearing ended on October 21, 2020, at 4:30 p.m., with 90 minutes remaining in the day. I did inform the parties that we would be finishing the hearing within the month of October, and to make their arrangements accordingly.

[6] *See* ALJ Ex. 65, Order Granting the Government's Motion for Partial Summary Disposition (June 18, 2020).

0880–02–.14(6)(e)(3)(i). Additionally, Rule 0880–02–.14(6)(e) requires physicians to create a ''written treatment plan tailored for the individual needs of the patient'' that considers the patient's ''pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.'' It also requires the physician to ''discuss the risks and benefits of the use of controlled substances,'' do a ''documented periodic review of the care . . . at reasonable intervals,'' and ''keep [c]omplete and accurate records of the care.'' *Id.* at 0880–02–.14(e)(3)(ii)–(v).

5. On October 3, 2017, the Respondent issued a prescription for 42-ten milligram tablets of oxycodone to UC, a Tennessee state law enforcement officer working in an undercover capacity. The Respondent issued this prescription following a brief meeting with UC, during which he performed a cursory and inadequate physical examination and reviewed medical records which did not justify the prescribing of oxycodone in the amount and dosage which he prescribed. He also failed to: (1) Take an adequate medical history; (2) assess the patient's pain, physical and psychological function; (3) assess the patient's history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of oxycodone. The Respondent further failed to create a legitimate written treatment plan for the patient's individual needs or discuss the risks and benefits of the use of oxycodone with the patient.

6. Additionally, on October 18, 2017, the Respondent's office provided UC with a prescription which the Respondent signed and dated October 18, 2017, for 84-ten milligram tablets of oxycodone. This occurred after UC paid $377 for an office visit during which no physical examination occurred and virtually no medical information was obtained or communicated. Additionally, on November 20, 2017, the Respondent's office provided UC with a prescription which he signed and dated November 20, 2017, for 84-ten milligram tablets of oxycodone. This occurred after UC paid for another office visit during which no physical examination occurred and no medical information was obtained or communicated.

7. With respect to the prescriptions the Respondent issued to UC, he issued these prescriptions without: (1) Taking a medical history or performing a minimally sufficient physical examination; (2) assessing the patient's pain, physical and psychological function; and (3) assessing the patient's history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of oxycodone. The Respondent further failed to create and follow a legitimate written treatment plan for the patient's individual needs or discuss the risks and benefits of the use of oxycodone with the patient. Also, by falsely indicating that UC was physically examined on October 18 and November 20 of 2017, he violated TENN. COMP. R. & REGS. 0880–02–.14(6)(e)(3)(v).

8. In addition to the medical records for UC, medical records for more than 20 of the Respondent's patients were reviewed by a qualified medical expert (''reviewing expert'') who concluded that the Respondent's continued prescribing of controlled substances to these patients was without a legitimate medical purpose and/or outside the usual course of professional practice. Below are examples of some of the patient records which were reviewed:

a. *Patient M.H.:* From August 2014 through February 2018, the Respondent regularly issued prescriptions for large quantities of alprazolam, carisoprodol, oxycodone, and oxymorphone to M.H. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
1.3.17	Alprazolam	.5 mg	120
1.4.17	Oxycodone	30 mg	84
1.4.17	Oxymorphone	15 mg	56
2.3.17	Alprazolam	.5 mg	112
2.6.17	Carisoprodol	350 mg	56
2.6.17	Oxycodone	30 mg	84
2.6.17	Oxymorphone	15 mg	56
3.3.17	Alprazolam	.5 mg	112
3.6.17	Oxycodone	30 mg	84
3.6.17	Carisoprodol	350 mg	56
3.6.17	Oxycodone	30 mg	84
3.6.17	Oxymorphone	15 mg	56
4.3.17	Alprazolam	.5 mg	112
4.4.17	Carisoprodol	350 mg	56
4.4.17	Oxycodone	30 mg	84
4.4.17	Oxymorphone	15 mg	56

According to the reviewing expert, the Respondent diagnosed M.H. with ''chronic pain syndrome'' even though he made no attempt to diagnose a specific pain etiology. The reviewing expert found that the Respondent failed to obtain diagnostic studies and current medical records from M.H.'s other medical providers and that the results of the Respondent's physical examination and medical history did not justify the continued prescribing of controlled substances. The reviewing expert also noted that he ignored a major surgical intervention that occurred in September 2016 as well as an abnormal drug screen. As such, the reviewing expert concluded that much of the medical record for M.H. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. The Respondent also documented that the patient provided ''informed consent,'' when no informed consent document could be located. The expert also found that, in some cases, the Respondent failed to repeat certain physical exams after his initial encounter with M.H., despite the fact he provided him with prescriptions for controlled substances for more than three years.

b. *Patient C.F.:* From August 2014 through August 2018, the Respondent regularly issued prescriptions for oxycodone and alprazolam to C.F. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
1.4.17	Alprazolam	.25 mg	28
1.6.17	Oxycodone	15 mg	84
1.30.17	Alprazolam	.25 mg	28
2.3.17	Oxycodone	15 mg	84
2.3.17	Oxycodone	7.5 mg	28
3.1.17	Alprazolam	.25 mg	28
3.1.17	Oxycodone	7.5 mg	28
3.4.17	Oxycodone	15 mg	84
3.13.17	Alprazolam	.25 mg	28
3.14.17	Oxycodone	15 mg	28
3.14.17	Oxycodone	7.5 mg	28
4.25.17	Alprazolam	.25 mg	28
4.28.17	Oxycodone	15 mg	21
4.28.17	Oxycodone	7.5mg	7
5.8.17	Oxycodone	15 mg	84
5.8.17	Oxycodone	7.5 mg	28

The reviewing expert found that no credible physical examination had been performed on C.F. and that the exam results, as well as medical history, did not justify the continued prescribing of controlled substances. The expert further found that no meaningful follow-up physical exam was repeated, that supported diagnostic studies were not ordered, and that the Respondent failed to determine a chronic pain etiology. The expert also found that he ignored suspicious drug screen results which indicated illegal drug use. The reviewing expert concluded that much of the medical record for C.F. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. The Respondent also documented that the patient provided ''informed consent'' when no informed consent document could be located.

c. *Patient M.P.:* From September 2016 through April 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone and oxymorphone to M.P. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
10.21.16	Oxycodone	30 mg	84
10.21.16	Oxymorphone	7.5 mg	56
11.18.16	Oxycodone	30 mg	84
11.18.16	Oxymorphone	7.5 mg	56
12.16.16	Oxycodone	30 mg	84
12.16.16	Oxymorphone	7.5 mg	56
11.22.17	Oxycodone	30 mg	84
11.22.17	Oxymorphone	7.5 mg	56
12.18.17	Oxycodone	30 mg	84
12.18.17	Oxymorphone	7.5 mg	56
1.19.18	Oxycodone	30 mg	84
1.19.18	Oxymorphone	7.5 mg	56
2.16.18	Oxycodone	30 mg	84
2.16.18	Oxymorphone	7.5 mg	56
3.16.18	Oxycodone	30 mg	84
3.16.18	Oxymorphone	7.5 mg	56

The reviewing expert found that he failed to request and obtain past medical records, he failed to order any radiographic studies, and that his physical examinations of M.P., including follow-up exams, were substandard and not credible. The expert found that he failed to document any evidence to support a pain etiology and that he failed to properly address M.P.'s substance abuse disorder despite the fact that she suffered a heroin overdose in his waiting room. As a result, the expert found no objective findings to justify the continued prescribing of oxycodone and oxymorphone. The reviewing expert also concluded that much of the medical record for M.P. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. He also documented that the patient provided ''informed consent'' when no informed consent document could be located.

d. *Patient B.C.:* From August 2014 through August 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone, oxymorphone, alprazolam, and carisoprodol to B.C. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
4.10.18	Alprazolam	1 mg	84
4.16.18	Oxycodone	30 mg	84
4.21.18	Oxymorphone	30 mg	56
4.27.18	Alprazolam	1 mg	84
5.14.18	Oxycodone	30 mg	21
5.21.18	Oxymorphone	30 mg	14
5.22.18	Oxycodone	30 mg	84
5.26.18	Oxymorphone	30 mg	56
6.12.18	Alprazolam	1 mg	5
6.12.18	Alprazolam	1 mg	84
6.19.18	Oxycodone	30 mg	21
6.22.18	Oxycodone	30 mg	84
6.22.18	Oxymorphone	30 gm	56
6.22.18	Carisoprodol	350 mg	56
7.9.18	Alprazolam	1 mg	84
7.25.18	Carisoprodol	350 mg	56
7.25.18	Oxycodone	30 mg	84
7.25.18	Oxymorphone	30 mg	56

The reviewing expert found that the physical examination and medical history did not justify the continued prescribing of controlled substances. The expert found that he failed to: (1) Obtain the patient's past medical records; (2) order radiologic and other studies that would support the treatment; (3) adequately address the fact that B.C. lied about his scheduled medications during his initial encounter; and (4) pursue a specific pain diagnosis. The expert also found that he failed to document the patient's response to the medication which he prescribed. The reviewing expert also concluded that much of the medical record for B.C. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments.

e. *Patient M.W.:* From January 2014 through August 2018, the Respondent regularly issued prescriptions for large quantities and dosages of oxycodone, oxymorphone, alprazolam, and carispoprodol to M.W. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
4.3.17	Alprazolam	2 mg	56
4.4.17	Carisoprodol	350 mg	28
4.4.17	Oxycodone	30 mg	56
4.4.17	Oxycodone	15 mg	56
4.28.17	Alprazolam	2 mg	56
5.2.17	Oxycodone	30 mg	56
5.26.17	Alprazolam	2 mg	56
7.7.17	Alprazolam	2 mg	56
7.31.17	Oxycodone	30 mg	56
8.4.17	Alprazolam	2 mg	56
10.18.17	Alprazolam	2 mg	56
12.12.17	Alprazolam	2 mg	56
1.19.18	Alprazolam	2 mg	56
2.12.18	Alprazolam	2 mg	56
3.30.18	Oxymorphone	15 mg	56
4.6.18	Alprazolam	2 mg	56
4.27.18	Oxycodone	30 mg	28
4.27.18	Oxymorphone	15 mg	56
5.15.18	Alprazolam	2 mg	56
5.29.18	Oxycodone	30 mg	28
5.29.18	Oxymorphone	15 mg	56
6.15.18	Alprazolam	2 mg	56
7.2.18	Oxycodone	30 mg	56
7.2.18	Oxymorphone	15 mg	56
8.29.18	Alprazolam	2 mg	56
8.29.18	Oxycodone	30 mg	56

With respect to M.W., the reviewing expert found that the initial physical examination and medical history did not justify the continued prescribing of controlled substances and the subsequent physical examinations did not meaningfully evidence any chronic pain condition. The expert also found that he failed to: (1) Order and obtain diagnostic studies; and (2) adequately address numerous instances in which the patient had abnormal drug screens indicating possible diversion, abuse, and/or use of illegal controlled substances. The reviewing expert also concluded that much of the medical record for M.W. was fabricated and seemed to be copied from records of

other patients whose records contained identically worded assessments. The Respondent also documented that the patient provided ''informed consent'' when no informed consent document could be located.

9. With respect to the Respondent's treatment of M.H., C.F., M.P., B.C., and M.W. (''the five patients''), the prescriptions for controlled substances which he issued were not issued in the course of professional practice inasmuch as he failed to: (1) Take an adequate medical history; (2) perform a sufficient physical examination; and (3) perform an adequate ''assessment and consideration of the [patients'] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.'' The Respondent also failed to create a ''written treatment plan tailored for the individual needs'' of each of the five patients which considered each of the patient's ''pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.'' He also failed to: (1) ''Discuss the risks and benefits of the use of controlled substances'' with patients M.H., C.F., M.P., B.C., and M.W.; (2) do a ''documented periodic review of the[ir] care . . . at reasonable intervals in view of the individual circumstances'' of each patient; and (3) keep ''[c]omplete and accurate records of the care provided.'' As such, his conduct violated TENN. CODE ANN. § 63–6–214(b)(12) and TENN. COMP. R. & REGS. 0880–02 .14(6)(e)(3)(i)–(v).

10. With respect to C.F., M.P., and M.W., the Respondent failed to address substantial evidence that the patients were engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. § 63–6–214(b)(l3).

11. The prescriptions the Respondent issued to UC, M.H., C.F., M.P., B.C., and M.W. failed to comply with Tennessee state law in that they did not conform to accept and prevailing medical standards in Tennessee, and thus, were issued outside the usual course of professional practice. His conduct, viewed as a whole, ''completely betrayed any semblance of legitimate medical treatment.'' *Jack A. Danton, D.O.,* 76 FR 60,900, 60,904 (2011). By issuing these prescriptions for controlled substances, he failed to take reasonable steps to guard against diversion of controlled substances. *See David A. Ruben, M.D.,* 78 FR 38,363, 38,382 (2013); *Beinvenido Tan, M.D.,* 76 FR 17,673, 17,689 (2011); *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,974 (2010); *Physicians Pharmacy, L.L.C.,* 77 FR 47,096 (2012).

12. Even a single act of knowing diversion is sufficient for the Agency to revoke a registration. *See Dewey C. Mackay,* 75 FR at 49,977. Detailed above are numerous acts of alleged unlawful prescribing, any one of which could independently establish the sort of intentional diversion on the part that would justify the revocation of his DEA registration and the denial of his pending application as inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4), 823(f).

13. In addition to the legal authorities cited above, the following cases and Final Orders provide a summary of the legal basis for this action: *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975); *Randall L. Wolff, M.D.,* 77 FR 5,106 (February 1, 2012); *Jack A. Danton, D.O.,* 76 FR 60,900 (September 30, 2011); *Robert F. Hunt, D.O.,* 75 FR 49,995 (August 16, 2010); *Linda Sue Cheek, M.D.,* 76 FR 66,972 (2011); *Kathy A. Moral,* 69 FR 59,956 (2004); *Rebecca Sotelo,* 70 FR 28,580 (2005); *Patrick W. Stodola, M.D.,* 85 FR 20,727 (2009); *Bob's Pharmacy and Diabetic Supplies,* 74 FR 19,599 (2009); *Nirmal Saran, M.D.,* 73 FR 78,827 (2008).

14. With regard to the Respondent's application for a new DEA COR in Kentucky, there are additional grounds for denying his application insofar as he lacks state authority to handle controlled substances in that state. On January 15, 2019, the Commonwealth of Kentucky, Board of Medical Licensure, issued an Emergency Order of Restriction prohibiting him from ''prescribing, dispensing, or otherwise professionally utilizing controlled substances.'' *See* 201 KY. ADMIN. REGS. 9:240 1 and 3. Thus, he is currently without authority to handle controlled substances in the Commonwealth of Kentucky, the state in which he has applied for a new DEA COR. Consequently, the DEA must deny his application for a DEA COR based on his lack of authority to handle controlled substances in the Commonwealth of Kentucky. 21 U.S.C. 824(a)(3); 21 CFR 1301.37(b). *See e.g., Kenneth C. Beal, Jr., D.D.S.* 83 FR 34,877 (2018); *Mehdi Nikparvarfard, M.D.,* 83 FR 14,503 (2018); *Leia A. Frickey, M.D.,* 82 FR 37,113 (2017); *Alaaeldin A. Babiker, M.D.,* 81 FR 50,723 (2016); *James Dustin Chaney, D.O.,* 81 FR 47,416 (2016); *Irwin August, D.O.,* 81 FR 3,158 (2016); *Wayne D. Longmore, M.D.,* 77 FR 67,669 (2012); *Jovencio L. Raneses, M.D.,* 75 FR 11,563 (2010); *John B. Freitas, D.O.,* 74 FR 17,524 (2009); *Worth S. Wilkinson, M.D.,* 71 FR 30,173 (2006).

Material Falsification

In its Supplemental Prehearing Statement, the Government alleged that, on November 6, 2019, the Respondent made a material falsification on his renewal application for his Tennessee-based DEA COR, #59889. Specifically, the Government alleged that in response to liability question three, the Respondent answered ''no'', which he knew or should have known to be a false response. GX 26. Liability question three queries whether the applicant has ever surrendered for cause, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or have any such action pending. The Government alleged that an affirmative answer to Question Three would trigger an investigation by a diversion investigator whether to issue the registration or to deny it. The Respondent answered ''No'' to question 3. A false ''no'' answer can result in an improperly issued registration. GX 26.

In support, the Government cites to the State of Tennessee Department of Health, Notice of Charges and Memorandum for Assessment of Civil Penalties, *see* GX 29, an order from the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part 3, reversing Denial of Stay, but Accompanying Stay with Conditions. GX 27. The Government contends that as of May 2019, the Conditions preclude the Respondent from writing prescriptions or providing direct patient care during the pendency of the stay. The Government also cites an Agreed Order with the State of Tennessee, GX 27, in which the Respondent was required to surrender his Pain Management Certificate, a professional license, in 2018, and prior to his application for registration in November, 2019. GX 26; GX 28. The Government alleges that, although GX 28 related to the surrender of the pain clinic license, and GX 26 was the Respondent's personal application, as the Respondent applied for the pain clinic license himself, it constitutes a surrender of his own license, warranting an affirmative response to Question Three of his DEA application. GX 26.[7]

The Hearing

Government's Opening Statement

The Government characterized the Respondent as a willing enabler of drug

[7] The surrender is signed by the Respondent individually.

abuse and diversion. Tr. 20. Rather than maintaining medical records lacking in detail, the Respondent's records, although detailed, were fabricated. The Government's expert reviewed twenty-four patient charts and discovered identical language throughout. Some phrases were repeated more than 100 times. Undercover [8] will testify that tests described in his chart were not performed. Test results were repeated during three visits in which he was not seen by the Respondent. The same identical test results were repeated in other patient charts. The Government's expert will testify that the Respondent prescribed controlled substances without a legitimate medical purpose and outside the usual course of professional practice, on the basis of the subject medical charts. He will further testify that the charts reveal multiple red flags of abuse and diversion, which were largely ignored by the Respondent. Rather, he created records which were deceptive, dishonest, and in some cases, dangerous. Tr. 20.

Respondent's Opening Statement

Samson Orusa contends that he is a fine physician, who cares deeply about his patients. Tr. 24. He spends a lot of time getting to know his patients to insure he understands their issues relating to pain management. His system is to use a number of documents, which the patients fill out prior to the Respondent seeing them, in order to get a full picture of each patient. These include the initial visit sheet, and a 41-page pain management physical exam sheet. He would go through these documents with the patient painstakingly. These forms take hours to fill out and to review.

The undercover agent presented himself to the Respondent under false colors, under an assumed identity, and with an MRI, which the Respondent could not confirm. He claimed to be from Missouri, a state without a PDMP. He reported he had used over-the-counter medications to treat his pain, and falsely claimed he had previously been prescribed Schedule II controlled substances, painting the picture that he needed Schedule II pain medications from the Respondent. The evidence will fail to show that the Respondent has done anything outside the bounds of normal medical practice.

Furthermore, the Government's case relies solely on the opinion of its expert, Dr. Kennedy, who we maintain is not an expert in the field of pain management, and whose qualifications are limited to family practice. He holds himself out to be a diplomat with the American Academy of Pain Management, which is a defunct organization. He has never completed a fellowship in pain management. He is not board-certified in pain management, and would not be qualified in the State of Tennessee to be a medical director of a pain clinic. The Respondent maintains Dr. Kennedy's opinion testimony should be afforded no weight in these proceedings.[9] Tr. 24

Government's Case-in-Chief

The Government presented its case-in-chief through the testimony of four witnesses. First, the Government presented UC. Secondly, the Government presented the testimony of Dr. Gene Kennedy. Thirdly, the Government presented the testimony of a DEA Special Agent assigned to this matter. Finally, the Government presented testimony of a DEA Diversion Investigator assigned to this matter.

Undercover

[UC testified regarding his education, credentials, and employment background with the Tennessee Bureau of Investigation].*C He has conducted approximately twenty to thirty investigations as the lead case agent in cases involving allegations of fraud, physicians prescribing narcotics without medical necessity, and physicians prescribing outside the scope of processional practice. Tr. 31–32. [Omitted.] [10] He provided lower back pain as a false symptom in this case, specifically because he has ''absolutely no back pain whatsoever.'' Tr. 112–11.

Undercover was contacted by a Special Agent (SA) with the United States Department of Health, Office of Inspector General (SA–DOH) who asked him to make an appointment with the Respondent in the late summer of 2017. Tr. 34; 98.[11] The initial goal in these types of cases is to get an appointment to see the doctor. Tr. 34. The ultimate goal is to see if the physician will write the undercover agent a prescription for a controlled substance. Tr. 34, 101.

In this particular investigation, UC contacted the Respondent's office and spoke with the receptionist over the phone, who told him that he would be scheduled for a new patient visit and was required to bring certain items on that day including; (1) an MRI report, (2) the last three chart notes from a previous physician, (3) the discharge summary from his previous pain management clinic, and (4) a printout of the last three months from his pharmacy. Tr. 35. UC already had some of the items, such as the MRI report, but there were other items he needed to put together. Tr. 34–35. The MRI that UC had was authentic, as it was his actual MRI that was performed on September 2, 2016. Tr. 35–37, 106. The only thing he altered was the ordering physician and patient name of ''Chris Rutledge.'' Tr. 35–37.

The patient records that he presented to the Respondent were fabricated. Tr. 37–38. DOH–SA and another SA consulted with a nurse practitioner who worked for TBI and instructed the agents to generate medical records that would be indicative of someone who was seeing a nurse practitioner for pain. Tr. 38, 108; GX 6. UC then provided his personal information including his date of birth and his medical complaints for the agent to create a medical record. The only medical record provided to the Respondent's office was signed by ''S.C.,'' who was not practicing medicine at that time. Tr. 38, 133.

UC visited the Respondent's office on October 3, 2017, and recorded video and audio of the visit. Tr. 40; 42–43.[12] He set up an appointment for 8:00 a.m. and was told to bring the necessary documents. Tr. 40. UC showed up for the appointment at approximately 8:00 a.m.[13] and gave the documents he had to the receptionist, and explained why he was missing two documents.[14] Tr. 38–40, 108; GX 4.[15] The receptionist gave him about twenty pages of paperwork and asked him to sit in the waiting room to fill it out. At some point he was called up by one of the

[8] [Omitted for privacy.]

[9] The Respondent's written motion to exclude the testimony of Dr. Kennedy was carried until the Government offered Dr. Kennedy as an expert witness at the hearing. Tr. 24–25, 26. The Respondent's Motion to Exclude was denied on its merits in conjunction with his objection to having Dr. Kennedy qualified as an expert witness. Tr. 201, 211–12. Contrary to the Respondent's claims, the motion was not denied as untimely.

*C In this section, I have omitted some biographical and investigation-related information to protect the identity and methodology of UC.

[10] [Omitted original text in which footnote appeared.]

[11] He is familiar with the DEA Physician's Manual. Tr. 98.

[12] At this point, Government offered Government Exhibit 3. The time stamp for the video of the October 3, 2017 visit is 5:05:42. Tr. 74.

[13] UC noted that he did not present in any ''unusual way'' to show that he had a disability, limp, change or change his gait. Tr. 46.

[14] As discussed *supra,* UC was asked to bring in a discharge summary, which is a report that a pain management clinic creates when the clinic releases a patient. Tr. 38–39, 108. He ultimately did not provide this document to the Respondent's office, stating that he was unable to obtain it. Tr. 39. He also stated that did not provide the printout showing the last three months of pharmaceutical history, because he was unable to get it. Tr. 39–40.

[15] No one asked for these records after his visit and he never produced the pharmacy records. Tr. 55.

employees [16] who made a comment about one of the pages in UC's medical record appeared to be ''whited out'' and the employee then made a statement that there are ''people that are trying to bring down [the Respondent]'' and the Respondent would therefore ''be reluctant to write any medications.'' Tr. 41; GX 3. The receptionist then told UC to have a seat and he would be called back for triage to get his vitals. Tr. 41–42, 44. UC paid for this visit with $311 of cash. Tr. 49, 110.[17]

UC filled out a pain disability index and ranked his pain level as a nine out of ten, which was not a truthful response to how he felt at the time. Tr. 47, 101, 109–10, 123. As to his goals, his second goal was to ''sleep through the night'' but he did not check the box for insomnia. Tr. 134–35, 139. Despite this contradiction, no one in the office asked about this. Tr. 139.[18] He also filled out a Zung Self-Rating Depression Scale, selecting random answers. Tr. 102. He also filled out a drug use questionnaire regarding his drug history with the intention of presenting a picture of a person who is in pain. Tr.102–03. He also filled out an agreement for opioid maintenance therapy and for cancer and non-cancer patients. Tr. 103. He also filled out an American Chronic Pain Association form including a chronic problem list and reported that he was only taking Advil, an over-the-counter, anti-inflammatory and pain medication of three pills, three times a day, with the understanding that if he was performing well with the over-the-counter medicine, a doctor would likely not give him a prescription. Tr. 103–105, 123. He also filled out a multi-page pain management physical form, which was blank [19] in his seized medical record. Tr. 105, 128. He could not recall if the Respondent went through every form with him, but did remember the Respondent asking him a couple questions. Tr. 105. He also recalled telling the Respondent that he had taken prescription hydrocodone in the past and it had helped him. Tr. 123.

At one point, a female wearing scrubs took his blood pressure, asked about his weight, provided him a specimen cup, and instructed him to go into the bathroom located inside the waiting room. Tr. 44–45. UC then produced a urine sample. Tr. 45.

The time that passed from when UC spoke with the employee about his ''fabricated'' records with the ''white-out'' page until he met with the Respondent, was about seven hours, only leaving the office for approximately forty-five minutes to get lunch. Tr. 48–49, 100.

[Omitted to protect law enforcement techniques]. UC told the Respondent where his pain was located and if it hurt he would respond that he had pain in that area, but did not make any face or wince. There was less than sixty seconds of any kind of physical touching between himself and the Respondent, which he testified was brief compared with other physicians.

The Respondent asked what his previous diagnosis was and he responded with arthritis and degenerative disk disease. Tr. 105–06.[20] During this visit, UC learned that the office staff had tried to contact his pharmacy and was unable to do so. Tr. 108–09. UC explained to the Respondent that he would try to get a hold of them and the Respondent's stated that his office would make another attempt. Tr. 109. They also discussed the alternative treatment of injections for UC's back pain, but UC refused to get the injections. Tr. 117, 127. UC told the Respondent that he had fallen off a truck sometime in 2013, was seeing Dr. Chapman in Pierce City, Missouri, and he moved to Tennessee about one month prior to his first visit on October 3, 2017. Tr. 117–18. None of these statements were true. Tr. 117–18. UC also shared a story about his aunt breaking her hip and him going to the clinic to obtain records, that he was unable to do so because the clinic was shut down, and that his aunt still lived in Missouri. Tr. 118. None of these statements were true. Tr. 118. UC admitted that he stated all of these lies in order to achieve his stated goal to get a prescription from this visit and also noted that ''[u]ndercover operations inherently rely upon some falsehoods in all aspects of law enforcement.'' Tr. 119–21.[21]

He received a prescription for 42 oxycodone 10-milligram tablets, thirty minutes after he left the exam room, from one of the receptionists, despite not asking for oxycodone. Tr. 56–57; GX 18. He also received prescriptions for Meloxicam and flexeril. Tr. 57–58; GX 18.[22] He filled the oxycodone prescription, but not the other prescriptions. Tr. 57, 58.[23]

UC went back to the office for a second visit on October 15, 2017, which was supposed to be his well-care visit between receiving his two narcotic prescriptions. Tr. 58–59. He did not make an appointment. He showed up at the office, and made a $25 payment to the receptionist. Tr. 59. He was called back to the triage room where the nurse asked him his weight, to which he replied, ''210,'' and if his blood pressure was ok, to which he responded, ''yes.'' The nurse then directed him back to the waiting room. He was later called to the exam room.

This visit was recorded in the same manner as the visit on October 3, 2017. Tr. 59–60; GX 4 at 4.[24] When he entered

[16] At this point in the testimony, Judge Dowd stated that UC was not allowed to read from his report directly. UC clarified that although he ''did have it open,'' he had not ''looked at it yet.'' Tr. 41.

[17] At this point in the testimony, the Government played a video. Tr. 51; GX 4. Judge Dowd instructed the court reporter not to transcribe the audio of the video, as the recording itself is the best evidence. UC confirmed that the transcript of the proceedings was a fair and accurate representation of the recording. Tr. 55; GX 4.

[18] UC had noted that he may have stated that he did not sleep well because he was awakened by his pain.

[19] UC noted that there were several forms that were blank in the copies he had.

[20] In fact, a physician had previously told UC that he may have arthritis, UC was not given a diagnosis of degenerative disk disease. Tr. 106–107.

[21] At this point in the testimony, on cross-examination, the Respondent's counsel made a comparison to an undercover agent purchasing heroin from a dealer and the Tribunal inquired of the Respondent's counsel as to the relevance of his questioning. Tr. 121. The Respondent's counsel asserted that UC had lied to the Respondent to achieve his goal of getting a prescription. Tr. 121. The Tribunal asserted that ''in principle this is an undercover operation. [That is] the whole point of it.'' Tr. 122.

[22] UC confirmed that this Government Exhibit 18 was a fair and accurate copy of the prescription he received on October 3, 2017.

[23] UC asserted that he did not expect to get controlled substances on this first visit, as he usually does not expect to get them, but from what he had ''been told regarding the clinic, it [did not] shock him.'' Tr. 125. If he had not received prescriptions that first visit, it would not have deterred him from making future appointments as it usually takes several appointments to build up to the point where the undercover agent receives controlled substances. Tr. 125. There is no set number for visits, but in cases where he has been the case agent, he has looked for a progression from other modalities of treatment first being offered and then elevating to drugs like hydrocodone to oxycodone, elevating the dosage or the quantities over time. Tr. 126–27.

[24] UC stated that Government Exhibit 4 is a transcript of his interaction with the Respondent on that date and is a fair and accurate representation of their encounter. Tr. 60; GX 4 at 4. The transcript reflects that the video was difficult to hear. The Respondent's counsel objected to the video being put into evidence if the video could not be properly played before the Tribunal. Tr. 64–66. The Tribunal noted the objection and allowed the Government's counsel to proceed. The video was replayed and UC asserted that he was able to hear the tape. The Tribunal overruled the objection and noted that the Respondent's counsel could cross examine UC. The Government later moved Government Exhibits 4 and 17 into the record. Tr. 69. The Tribunal admitted pages 1, 2, and 3 of Exhibit 4 and part of Government Exhibit 17, but noted that it was ''not convinced that [the] audio is intelligible, fully audible, without interference, because [it] ha[s] nothing but interference'' on the Tribunal's end. Tr. 70. On Day 3 of the hearing, the Tribunal reconsidered its earlier ruling on the limited admissibility of GX 4 and 17, and admitted the exhibits in their entirety, noting that the video/audio (GX 4) was played successfully at the hearing to all participants, except the Tribunal and court

the room, the Respondent asked if it was UC's first well visit or primary care visit and UC affirmed it was. Tr. 71. The Respondent asked if UC was taking other medications and he stated that he was not taking medications other than pain medications. The Respondent asked whether UC was sleeping well and he responded ''not really.'' The Respondent then stated that he would write him a prescription for pain medications to help him sleep. UC asked what it was, and the Respondent stated, ''amitriptyline.'' That marked the end of the encounter. Tr. 71. There was no further medical examination or physical examination of his lower back, of any of his extremities, or an examination to determine if he had muscle pain. Tr. 71–72.

UC had a third visit on October 18, 2017, when he was scheduled to get the refills for his narcotic medications. Tr. 75. He went to the Respondent's office and first attempted to pay with cash, but had to secure a debit card. Tr. 75–76. He wrote his name on a clipboard, paid the $377 fee for the office visit, and about an hour later his name was called and he got his prescription. Tr. 76. He was at the clinic for approximately two and half hours and was not examined by any medical personnel nor did he provide any medical records. Tr. 77. He received a prescription for eighty-four tablets of ten milligrams of oxycodone. Tr. 78, GX 18 at 3, 4. This dosage was less than the Lortab of four times a day. He also received the ''euphoria drug'' of Xanax that he had falsely claimed he was receiving in Missouri. Tr. 112.

Upon reviewing the medical records, UC noted that despite his records stating that ''Mr. Rutledge . . . has had a history of insomnia and anxiety for several years,'' he did not report anxiety symptoms of shortness of breath, of having palpitations, sweating, dizziness, or shaking. Tr. 79–80; GX 5. The medical record also reflects that he had a headache that day, despite the fact that UC did not report having a headache, dizziness, nausea, or vomiting. Tr. 80; GX 5. No one questioned UC as to whether he had abdominal pain, diarrhea, and constipation. Tr. 80–81. UC reviewed Government Exhibit 5 and noted that he was not asked about any of these symptoms. Tr. 81. He also assumes that the office accessed and checked the Tennessee controlled substance data bank on his first visit as this was in his medical records, but he was not specifically informed of it. Tr. 110. He also believes that the UC's assumed identity has never had a controlled substance filled in Tennessee. Tr. 111. He also believes there was no Missouri prescription database at that time, where he asserted he was from, so the office could not obtain information from there. And the fact that Missouri did not have a state-controlled prescription monitoring program in Missouri was a factor as to why the persona of UC's assumed identity was somebody from Missouri. Tr. 110–11.

At the appointment on October 17, 2017, UC did not have his blood pressure checked, was not weighed, did not have his chest examined, and did not have his breathing measured or evaluated. Tr. 82. On October 18, 2017, UC did not discuss muscle pain, back pain, nor a Review of Systems (ROS). Tr. 82–83. No one examined his chest, or his breathing. Tr. 83.

UC had another visit on November 15, 2017, which was another well-visit. Tr. 84. He paid $25, waited for some time, was called back and asked about his weight and if his blood pressure was okay. He specifically asked the nurse if he was dismissed and after she said yes, he left. He did not receive any prescriptions that day. Tr. 85. Despite what the medical records say regarding this visit, there was no medical examination conducted on that day, including of his chest, or breathing. Tr. 86, 90; GX 5.

UC had another visit on November 20, 2017, for a medication visit. Tr. 87; GX at 10. UC walked in, put his name on a clip board, paid some money, waited a certain amount of time for his name to be called, and went to the window to obtain his prescriptions. Tr. 88. On this particular day, he was asked to provide a urine sample. Tr. 88, 92. He received a cup from the nurse, went into the bathroom for his unsupervised urine test, and provided a urine sample. He had brought a vial of a substance that would cause him to test positive for Oxycodone, put that in the urine sample, and returned the sample to the nurse as instructed. Tr. 88, 92; GX 3. He believes that, despite the added substance, his urine drug screen came back negative *D and the Respondent never discussed this screen with UC nor did anyone else at the practice. Tr. 91–92; GX 3.[25] He received a prescription for oxycodone for eighty-four tablets of ten milligrams from one of the receptionists, who provided the prescription to him as well as several others. Tr. 89. GX 18 at 4. UC did not meet with the Respondent that day. The medical records say ROS, but none of the systems were examined during this visit. Tr. 91.

Besides verbalizing and writing down that his pain was nine out of ten, UC did not do anything to indicate that his pain was actually that level. Tr. 94–95; GX 3, 18. He did not present any falsified records showing he had a history of filling controlled substance prescriptions in any state[26] and never produced pharmacy records showing his prescription history. Tr. 133. In UC's experience of working with people who abuse drugs or obtain drugs to sell them, he has found that these people are pretty savvy about filling out their forms when they go to the doctor. Tr. 133–34.

Dr. Gene Kennedy

Dr. Kennedy, who is licensed in Georgia, is a family practitioner by training and has treated patients for pain since being licensed. Tr. 202. Dr. Kennedy was offered, and qualified, as an expert in the field of pain management. Tr. 201, 211–12, 216. Although not board certified in pain management, he has been treating people for pain full-time since 2004 or 2005, when he opened his own pain management clinic. Tr. 178–80, 202–03, 427.[27] He has treated all types of pain patients: Patients suffering acute post-surgical pain; patients suffering from back pain; cancer patients; and patients referred by other pain management physicians. Tr. 180–81, 355. He has prescribed assorted controlled substances, including opioids to treat pain, including Schedule I. Tr. 181. He treats patients over 120 MME. He noted only UC and C.F. were being treated below 120 MME. Tr. 427–28. He has

reporter, which the Tribunal attributed to a VTC issue and not to a defect in the DVD itself. [I have reviewed the contents of the DVD and find that the videos play successfully.]

*D The Government did not fully explain this portion of its case which I find to be immaterial. Ultimately, inconsistent UDS results were not relevant to Dr. Kennedy's opinion that the prescriptions issued to UC were issued outside of the standard of care nor were they relevant to my findings in this decision.

[25] Although the Respondent objected to Government Exhibit 3 being offered into evidence based on hearsay, the Tribunal overruled the objection finding that any hearsay statements in this exhibit have been properly authenticated. Tr. 94. The Tribunal also noted that UC could be cross-examined regarding his report.

[26] UC noted in the Patient Pain History form that he had previous medications including hydrocodone between November 2016 and September 2017, Xanax from approximately August 16, 2016 through September 2017, and oxycodone from August 2017 to September 2017.

[27] Although not dispositive in this setting, Dr. Kennedy's credentials would not permit him to be a director of a pain clinic in Tennessee, without annually consulting with a board certified pain management specialist. Tr. 204–05, 428–30.

prescribed benzodiazepines. He performs pain injections. Tr. 357.

He has previously been qualified as an expert witness in administrative hearings of the Alabama Medical Board, the Georgia Medical Board, DEA, FBI and DOJ. On thirteen occasions he has testified regarding whether a physician has properly prescribed controlled substances. GX 24. He has served as an adjunct lecturer regarding the proper prescribing of controlled substances to DEA, at the National Advocacy Center, and on behalf of the DOJ. Tr. 185. He estimated over half of his income comes from the work and lectures given to Government agencies. Tr. 359. In 2018, he estimates he was paid over $100,000 by the Government. Tr. 432. For the instant case, he is being paid $450 per hour for an estimated forty hours of preparation plus courtroom hours. Tr. 434–36. He has also lectured regarding the PDMP to medical residents and physicians and taught a course to pharmacists in Tennessee regarding legitimate prescribing. Tr. 185. He is familiar with Tennessee law pertaining to prescribing controlled substances, and has relied on the following sources in developing his opinions herein: Tennessee Pain Clinic Guidelines, the Federation of State Model Policy, AMA Guidelines, the DEA Practitioner's Manual. Tr. 183, 360–62. He was hired by the DEA to offer an expert opinion on the Respondent's prescribing and of the medical practice, on the basis of material the government provided him. This material included approximately twenty charts, surveillance videos, and pharmacy reports. The surveillance videos involved undercover encounters between UC and the Respondent. Tr. 184; GX 8–23.

Dr. Kennedy is familiar with the standard of care for a physician prescribing controlled substances in Tennessee. This standard requires an adequate medical history, including all the historical information helpful in developing a diagnosis, course of treatment and in understanding the risks involved. Tr. 189, 195. The standard requires diagnostic testing, if indicated. Tr. 196. The standard requires the physician to perform a physical exam. Tr. 190, 200–01. The standard requires a physician to maintain medical records for patients to whom controlled substances are prescribed. Tr. 196. These medical records should contain a pain history, a history of drug abuse and termination by other physicians, a physical exam pertinent to the patient's complaint, efforts at obtaining state pharmacy reports, the physician's thoughtful assessment of the patient's condition, and an individualized treatment plan. Tr. 196–98. Dr. Kennedy noted the importance of maintaining complete and accurate patient records. Tr. 353. With patients sometimes on high doses of potentially dangerous controlled substances, the charts must be accurate and honest, so any practitioner who views the charts can make an accurate assessment of the patient's conditions. Tr. 353–54.

In reviewing the subject medical records, Dr. Kennedy recognized indications of possible abuse and diversion, including patients unable to produce past medical records, a cloudy history of drug abuse. Tr. 191–92. Dr. Kennedy noted that the Tennessee standard precludes a physician from prescribing controlled substances to a patient with a habit of improperly using them, without first making a bona fide effort to cure the patient's addiction. Tr. 199. When a benzodiazepine and an opioid are prescribed in combination, the physician would have a heightened sense of vigilance, which would need to be documented within the chart. Tr. 190. Urine drug screening (UDS) is a common practice in pain management treatment. Tr. 192. It can reveal whether a patient is taking a medication he is prescribed and whether he is taking medications or illegal drugs he is not prescribed. Tr. 193–94. The standard of care would require, at minimum, that the physician document in the records the inconsistent UDS, and describe his plan of action. Tr. 194–95.

Dr. Kennedy reviewed the chart and the undercover videos for Patient UC, who was the undercover agent. Tr. 216–17, 363; GX 6. Dr. Kennedy acknowledged that in scheduling the first visit, the Respondent's staff instructed UC to bring certain medical records to his first visit: The previous three physician notes, his discharge summary, the record of the previous three months prescriptions and an MRI, an appropriate protocol in Dr. Kennedy's opinion. Tr. 364–65; GX 3 at 1. Dr. Kennedy did not believe the medical chart justified the prescribing of controlled substances. Tr. 230–31, 240; GX 18 at 1, 3. Although an actual MRI report of UC, Dr. Kennedy found the MRI report internally inconsistent, which did not justify controlled substance medication. Tr. 387–94, 483–86. UC was being treated for complaints of back pain. However, Dr. Kennedy opined that the physical exam detailed in the chart was not sufficient under Tennessee standards, and the exam performed revealed a normal back.*[E] Tr. 217, 231, 237, 396–97, 440. On rebuttal, Dr. Kennedy reiterated this assessment after listening to the Respondent's explanation. Tr. 651–52. After filling out extensive paperwork, the initial examination by the Respondent consisted of observing the UC, touching his back and causing the patient to lift his leg. Tr. 217–18, 359–60; GX 6 at 6. Dr. Kennedy did not believe UC's chart reflected the Respondent maintained a truthful and accurate record of the treatment. Tr. 232; GX 3; 4. Dr. Kennedy noted the taking of vital signs and a general exam within the chart, however he observed that from viewing the video of this visit, such exam was not performed as described, or not performed at all. Tr. 218–19, 232–33, 379–81; GX 6 at 4. The prior medical history reported by UC, was facially suspicious and constituted a red flag. Tr. 238. UC reportedly, came from a clinic, which has since shut down, and provided medical records from a Nurse Practitioner, whose license has been suspended. Tr. 238. Dr. Kennedy opined that UC's obfuscation, false and misleading statements to the Respondent and staff, did not relieve the Respondent's obligation to investigate any suspicious circumstances. Tr. 375–78, 382.

Dr. Kennedy noted that the physical exam included in this first visit by UC was repeated verbatim in most of the 20 or so charts he reviewed. Tr. 220; GX 7 at 65 (M.B.), GX 9 at 69 (M.W.). Dr. Kennedy noted UC's chart identified him with a ''long-standing history of insomnia and anxiety,'' however the chart contained no examination, which would support such findings. Tr. 233–34; GX 5 at 4. Additionally, the reported symptoms of the anxiety finding, ''palpitations, sweating, dizziness, shaking'' was repeated almost universally throughout the medical records reviewed as to patients diagnosed with insomnia and anxiety. Tr. 233–34. Although UC reported his pain level at 9 or 10, the exam results do not support that, nor did the video of this encounter. Tr. 234–35, 238. Similarly, the visit of October 17, 2017, by UC contains extensive medical findings, although the video of that visit does not support those findings. Tr. 235–37; GX 5 at 5. The video does reveal the Respondent asking UC, ''how is your sleep,'' to which UC responds, ''not good.'' Tr. 236. The Respondent

*[E] Dr. Kennedy testified that an adequate back exam would have required Respondent to look ''for something that is out of place, muscle spasms, . . . perform lumbar range of motion maneuvers where the patient essentially bends at the waist in various directions. Additionally, . . . a straight leg raised test, . . . neurologic exam, which makes comment on their motor deficits and their sensorium as pertains to their complaint of low back pain.''

then prescribed Elavil, also called amitriptyline. Tr. 236. Dr. Kennedy made a similar observation as to extensive medical findings on subsequent visits, in which UC was not seen by the Respondent. Tr. 235–37; GX 5 at 3–5. Although the medical records reflect physical examination took place at the level one visits, the Respondent explained that it was permissible in medical record-keeping to carry forward results from prior examinations to later visit records, with new findings added. Tr. 623–28. Dr. Kennedy disagreed, noting that it is never permissible for charts to reflect examination results, when no exam occurred. Tr. 652–53.

On the basis of the deficient physical exam, Dr. Kennedy opined that prescribing controlled substances to UC was not justified.*F Although the Respondent prescribed a much lower MME than UC had purportedly been on previously, it was not consistent with the Tennessee standard, which would include observation, looking for spasms, lumbar range of motion maneuvers, straight leg raise test, neurologic exam and motor deficits. Tr. 221–25, 239, 382–83; GX 5 at 6. Other deficiencies in the records that caused the controlled substance prescriptions for UC to be unjustified included the deficiency in the prior medical records provided by UC Tr. 228. UC's chart revealed an exploration of alternate treatment, by prescribing Meloxicam. Tr. 228–29. However, UC's chart did not include an adequate treatment plan. Tr. 229. The records reveal a deficient discussion regarding the risks and benefits of controlled substance medication. Tr. 231. Dr. Kennedy deemed the diagnosis of degenerative disc disease unjustified on the basis of the chart and MRI. Tr. 240–42; GX 5 at 2, 6; GX 6 at 12.

Dr. Kennedy prepared reports or charts containing his review of the relevant medical evidence in this case. His findings accurately reflect the original medical records, which are in evidence. His chart was admitted as a chart of voluminous records under Fed. R. Evid. 1006. Tr. 225–28; GX 6 at 2.

Patient M.W.

Dr. Kennedy identified his ''chart review'' for M.W. Tr. 243–44; GX 9, 10. M.W. was diagnosed with low back pain, yet Dr. Kennedy opined that the records did not support such diagnosis. Tr. 245–46; GX 9 at 14; GX 10 at 3. The notes did reference back to M.W.'s initial encounter. Tr. 441. There were no findings in the record which would support a chronic pain condition and justify prescribing controlled substances. Tr. 246–47. Dr. Kennedy found no credible physical exam to justify the diagnosis. Tr. 247, 265. The Respondent did not assess M.W.'s pain level, physical and psychological functioning, history, potential for drug abuse, or coexisting diseases. Tr. 265. The Respondent did not follow a legitimate treatment plan. Tr. 265. The physical exam findings were generally normal findings, except for limited range of motion at the lumbar spine. Tr. 247; GX 10 at 7. M.W. reported a pain level, at worst, at 10 of 10, and at best, 6 of 10. Tr. 248–49; GX 9 at 19; GX 10 at 8. M.W.'s reported pain level was inconsistent with the generally normal results of the physical exam. Tr. 249–50.

The electronic medical record for this visit does not contain the handwritten information recorded in GX 10 at 8. Tr. 250–51; GX 10 at 9. Instead, the results of the physical exam mirror those findings made for UC, rendering M.W.'s chart not credible. Tr. 251–52. Additionally, the record contained ''wildly abnormal'' *G UDS results that were ''not meaningfully addressed.'' Tr. 252–55; GX 9 at 2–4, 9–11, 84, 96, 102. After a series of inconsistent UDS, the Respondent noted in M.W.'s chart that M.W. was dismissed from pain management with one month notice. Tr. 258; GX 9 at 84. Yet, at the same visit in which he had been notified he would be dismissed, the history of present illness (HPI) reports patient is compliant and consistent. Tr. 258. Dr. Kennedy deemed the chart not credible, accordingly. Tr. 259. However, despite being dismissed, M.W. continued to be seen for months afterwards, without any further explanation. Tr. 259–60. Dr. Kennedy later conceded that M.W. was reinstated consistent with the Respondent's office protocol. Tr. 449–50. The Respondent continued to prescribe him Alprazalam, amitriptyline, oxycodone, oxymorphone and Soma. Regarding the Alprazalam prescription, Dr. Kennedy found it unjustified based on the information supporting the anxiety diagnosis. Tr. 260–61, 442–44; Tr. 261; GX 9 at 85. Dr. Kennedy noted the indications for anxiety were not supported by the findings within the chart, and mirrored those in the charts for UC and the other patients. Tr. 261–62. Although Dr. Kennedy opined M.W. should have been physically examined ''on a regular basis'' during his treatment, the charts suggest he was not examined again following his first examination.*H Tr. 262. Dr. Kennedy further opined that as M.W. was a 25 year-old diagnosed with degenerative disc disease, the Tennessee standards would require diagnostic testing, such as an MRI to confirm the diagnosis. Tr. 262, 447–48. Dr. Kennedy found M.W.'s chart ''not credible and fabricated.'' Tr. 263–64, 266; GX 10 at 5, 23. He noted that of 93 of 98 total visits shared the identical findings for the physical exams and ROS. Tr. 264. Similarly, Dr. Kennedy found the diagnosis of insomnia not credible. Tr. 264. A finding of drug abuse and chemical dependency would have been supportable, but such indications were not sufficiently addressed by the Respondent. Tr. 264–65. The credible findings within M.W.'s chart did not support the prescribing of controlled substances,*I and the subject prescriptions were issued without medical justification and outside the usual course of professional practice. Tr. 266–68.

Patient C.F.

Dr. Kennedy identified the summary chart he prepared on Patent C.F. Tr. 268; GX 12. C.F. was being treated for chronic pain due to trauma, unspecified inflammatory polyarthropathy. C.F. had suffered stab wounds to the chest requiring open heart surgery, which can cause long-term neuropathic pain. Tr. 451–53. Dr. Kennedy opined the history,

*F Dr. Kennedy actually offered several bases for his opinion that all of the controlled substances Respondent prescribed to C.R. were issued outside the usual course of professional practice. Tr. 239. Specifically, Dr. Kennedy identified Respondent's failures to perform a sufficient physical examination; to adequately assess the patient's pain, physical, and psychological function; to sufficiently examine the patient's history; to assess a recognized medical indication for the use of oxycodone; to create or follow a legitimate written treatment plan; to discuss the risks and benefits of using oxycodone with the patient; to maintain truthful and accurate medical records; or to resolve red flags arising from the medical records C.R. provided, which stated that C.R. had been treated at a clinic that had closed by a nurse practitioner, whose license had been suspended. Tr. 237–39.

*G For example, regarding the UDS at GX 9, 2–4, M.W. was prescribed oxycodone, carisoprodol, alprazolam, and ozymorphone. GX 9, 2–4. The drug screen results were negative for the prescribed drugs alprazolam and carisoprodol and, as Dr. Kennedy testified, positive for non-prescribed substances including ''morphine, positive for hydromorphone, positive for oxymorphone, . . . positive for THC. . . .'' Tr. 251–52.

*H Dr. Kennedy testified that the little documentation there was suggesting a physical exam could have been performed was ''not credible'' because it was ''repeated documentation that we have described before.'' Tr. 262.

*I Specifically, Dr. Kennedy testified that Respondent failed: To perform a sufficient physical examination; to adequately assess the patient's pain, physical, and psychological function; to sufficiently examine the patient's history and potential for substance abuse; to identify a recognized medical indication for the use of the controlled substance prescriptions; to create or follow a legitimate written treatment plan; and to adequately address M.W.'s exhibited evidence of drug abuse. Tr. 264–66.

physical exams, the pain and physical and psychological functioning, the potential for substance abuse, written treatment plan, and alternate treatment considerations were inadequate, and did not justify the controlled substance prescriptions. Tr. 269–70, 285, 455; GX 11 at 106; GX 12 at 7. The Respondent did not discuss the risks and benefits of controlled substance medications [and did not keep accurate records of the care he provided.] Tr. 285–86. The physical exam notes revealed essentially normal findings, however the electronic records for this visit failed to include these findings. Tr. 271; GX 11 at 69. Instead, under physical exam, the same language often duplicated in the records, is included. Tr. 272. There were no credible follow up physical exams, supporting studies, and no reasonable pain etiology. Tr. 272; GX 12 at 5, 6. The ROS indications were identically repeated in other charts. Tr. 272–73. Dr. Kennedy noted that the language in the general exam, ''patient is alert and oriented'' is similarly repeated 102 times throughout the records. Dr. Kennedy reported an inconsistent UDS for C.F., collected on July 2, 2018, and many thereafter. Tr. 273–80, 282; GX 11 at 9, 23, 24, 25, 28, 33, 44, 47, 54, 69, 78, 111, 117; GX 20. C.F.'s UDS result was negative for all of the medications he was prescribed. Tr. 275–77. C.F. also tested positive for cocaine and marijuana. Tr. 277, 280. An inconsistent drug screen on July 26, 2017, is not mentioned in the medical records. Tr. 288–89. Although the records repeatedly noted that, ''patient counseled at length on unsatisfactory UDS,'' this was insufficient under Tennessee standards in addressing C.F.'s drug abuse and diversion [because it did not document ''anything specific.''] Tr. 280, 284. On May 3, 2017, C.F. tested positive for buprenorphine, a medication typically used for opioid use disorder. Tr. 281–82. The Respondent had not prescribed it [and failed to investigate or address the issue.] Tr. 282. Dr. Kennedy opined that the Respondent continued to improperly prescribe controlled substance without making a bona fide effort to cure C.F.'s addiction. Tr. 284. The Respondent prescribed alprazolam for anxiety and insomnia. Tr. 286; GX 11 at 39. However, the supporting indications are identical to the other patients who were diagnosed with anxiety and insomnia. Tr. 286–87. The Respondent did not maintain complete and accurate records for C.F. Tr. 286. Dr. Kennedy concluded that the controlled substance prescriptions to C.F. were outside the usual course of professional practice. Tr. 287.

Patient B.C.

Dr. Kennedy identified his summary chart for B.C. Tr. 289–90; GX 13; GX 14. B.C. was being treated for chronic pain syndrome. B.C. was referred from the Clark County Jail, a potentially challenging patient. Tr. 458–59. The Respondent did not take an adequate medical history. Tr. 304. Although documentation of some physical exam was evident, it was insufficient and non-supportive to justify prescribing the medications prescribed.*[J] Tr. 290–91, 304; GX 13 at 169; GX 14 at 7; GX 22. He did not make an adequate assessment of pain, physical and psychological function, history of substance abuse, coexisting diseases and conditions, written treatment plan, or alternate treatments. Tr. 304–06. He did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 306. There were no radiologic studies ordered. Tr. 303. There were no prior medical records ordered or obtained, yet the records did include hospital records. Tr. 303, 459–60. Dr. Kennedy noted indications from the ROS were duplicated throughout the records. Of 141 encounters, the ROS language was duplicated 140 times, while the physical exam language was duplicated 134 times. Tr. 291–92. He did not maintain accurate and complete records. Tr. 306. B.C. had serious health issues, including Hodgkins lymphoma, a cancer of the lymphatic system. Tr. 293. Dr. Kennedy identified a document in the chart indicating B.C. had been dismissed from a prior physician, a clear red flag [for which there was no ''evidence in the medical record that [the] red flag was investigated.''] Tr. 293–94; GX 13 at 188.

Dr. Kennedy noted that B.C.'s pain level was left blank in the medical record for nine consecutive encounters, suggesting [''that [the] information is not actually being obtained and that the documentation is simply being inserted in the chart.''] Tr. 294–95; GX 13 at 159; GX 14 at 8. One entry reveals, ''patient lied about his prescriptions,'' an alarming red flag left unaddressed by the Respondent. Tr. 296; GX 13 at 169. Despite noting that the ''patient lied,'' the Respondent issued controlled medications and ''held'' up UDS for a month. Tr. 297. Dr. Kennedy opined that this prescribing was outside the usual course of professional practice. B.C. continued to have inconsistent UDS results, which were insufficiently addressed by the Respondent.*[K] Tr. 297–98; GX 13 at 33, 79, 150, 155, 156, 158, 164, 165. The information contained in B.C.'s chart did not justify the controlled medications prescribed by the Respondent, nor support that they were issued in the usual course of professional practice. Tr. 307–08.

Patient M.H.

Dr. Kennedy identified his summary chart for Patient M.H. Tr. 309; GX 15; GX 16. M.H. was being treated for chronic pain syndrome. GX 15 at 62, 63. The physical exam indications are identical to those repeated throughout the medical records. Tr. 311. The indications do not support any chronic pain diagnosis. Tr. 311. The records reveal M.H. suffered a gunshot wound in 2008, and although serious, would not in itself justify pain medication eight years later. Tr. 323. Dr. Kennedy assessed the Respondent's treatment as outside the scope of acceptable medical practice.*[L] Tr. 312. He did not make an adequate assessment of pain, and physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan or alternate treatments. Tr. 326–28. He did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 328. M.H. had inconsistent UDS. Tr. 314–20; GX 15 at 36, 39, 40, 47, 49, 53, 56, 63. Although several inconsistent UDS were noted in the chart, they were not typically mentioned. The Respondent failed to adequately address the UDS. Tr. 314–20.

During his treatment with the Respondent, M.H. underwent a serious and complex spinal surgery, a major surgery. Tr. 320–22, 462–63. GX 15 at 26; GX 16 at 9. M.H. was seen by the Respondent the day after his release

*[J] Dr. Kennedy testified that the documented physical exam was insufficient, because ''there are no positive objective physical findings that rise to the level of requiring medications prescribed.'' Tr. 291. He further testified, that based on B.C.'s known medical problems, ''[it is] not impossible that this patient had a chronic pain condition. But I would note that over the course of 140 encounters the chart does not mention, . . . on a single occasion where [we are] consistently talking about what specific pain the patient is experiencing.'' Tr. 305. Accordingly, Dr. Kennedy testified, the medical record did not support a recognized medical indication for the use of the prescribed controlled substances. *Id.*

*[K] According to Dr. Kennedy, the medical records say ''the patient is counseled at length, but again, [there is] nothing specific about what the counseling entailed or any decision made based on it.'' Tr. 301.

*[L] My findings in this matter are based solely on Respondent's prescribing of controlled substances, not Respondent's prescribing of non-controlled substances or his overall treatment of patients.

from the hospital. GX 15 at 48. Despite his recent, major surgery, there is no mention of the surgery in the encounter notes.*[M] Tr. 322–23. The encounter notes are identical to all the other encounter notes reviewed. Tr. 323; GX 15 at 48. There is no updated physical exam, as would be required by the standard of care. Tr. 324. The PE and HPI notes are the same as those the 4 months prior to the spinal surgery, which is not credible. Tr. 324–25, 491–92; GX 15 at 49, 51. The Respondent did not maintain accurate and complete records as to M.H. Tr. 328. Dr. Kennedy reviewed the prescriptions issued. Tr. 325; GX 19 at 1–13. He opined that the chart, including the number of inconsistent UDS, reveals that there was ''a significant probability'' that M.H. was addicted to the habit of using controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction. Tr. 325. The subject prescriptions were issued outside the usual course of professional practice. Tr. 329–30, 493.

Patient M.P.

Dr. Kennedy identified his summary chart for Patient M.P. Tr. 331; GX 8. M.P. was being treated for low back, neck, hip and shoulder pain. She was later diagnosed with degenerative disc disease and right shoulder pain. Although a physical exam was performed, it was inadequate to substantiate the diagnoses. Tr. 331–34, 339–40, 343; GX 7 at 2. A mechanical shoulder exam and range of motion back and neck exam should have been performed. Tr. 335. He did not make an adequate assessment of pain, nor physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan nor alternate treatments. Tr. 349–51. He did not conduct any periodic reviews, nor discuss the risks and benefits of the use of controlled substances. Tr. 349–50. Her employment as a server, working forty to sixty-five hours per week is inconsistent with her ''occupational disability'' score of 9 or 10, which Dr. Kennedy described as a significant conflict. Tr. 344–45; GX 7 at 3, 9, 10. Dr. Kennedy noted the hand-written exam notes did not appear in the electronic medical records, Tr. 325–36; GX 7 at 68, rather, the medical records reflected the same PE notes duplicated throughout the medical records for all of the patients at issue. Tr. 336, 351. The pain level is reported as 9, which is inconsistent with the PE indications. Dr. Kennedy indicated notes generated at the initial visit appeared to be a reminder to obtain certain prior medical records from Dr. M. Tr. 337, 468; GX 7 at 1, 68. Those same notes appear in the record repeatedly thereafter. Tr. 337; GX 7 at 59. Other than the requested pharmacy report, the prior records were never obtained. Tr. 338–39. The Respondent did not maintain accurate and complete records as to M.P., [and the chart contained language that was verbatim as other medical charts.] Tr. 350–51.

At M.P.'s initial visit, a UDS was performed revealing inconsistent results, which were never addressed in the records. Tr. 338; GX 7 at 19, 68. Notes reveal M.P. had been terminated from a prior physician, which is a red flag. Tr. 343. The records did reveal a monitoring of the Tennessee PDMP, and a successful pill count. Tr. 470. There were emergency room notes, which revealed she was admitted on April 17, 2018, and released on April 18 for apparent heroin overdose, which occurred in the Respondent's waiting room. Tr. 340–41; GX 7 at 25. [Dr. Kennedy testified that, aside from the ER records, ''there is not a note in the chart that specifically refers to this patient overdosing or going unresponsive in the waiting room.'' Tr. 341.] At the next encounter, the Respondent discontinued the previous prescriptions for controlled substances, discussed drug rehab with M.P., which she declined to pursue, and prescribed buprenorphine, an opioid abuse treatment. Tr. 342. Dr. Kennedy viewed this course of action as dangerous and outside the standard. Tr. 342, 371–73, 465–66. As the patient was shown to be on heroin, a UDS would be necessary to determine if she had heroin in her system before prescribing buprenorphine, which in conjunction with heroin could result in permanent withdrawal. Tr. 343. There were inconsistent UDS in the records for M.P. Tr. 346; GX 7 at 48, 59.

Dr. Kennedy reviewed the prescriptions issued. Tr. 348–49; GX 21. He opined that the chart, including the number of inconsistent UDS, reveals that [Respondent should have been concerned that M.P. had a habit of being] addicted to controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction, until after she overdosed on heroin. Tr. 348. The subject prescriptions, as well as those prescribed to the other charged patients, were dangerous *[N] and were issued without medical justification and outside the usual course of professional practice. Tr. 352, 488–89.

DEA Special Agent (SA1)

SA1 is a Special Agent with the Drug Enforcement Administration, and has been for ten years. Tr. 498. He attended the Special Agent Academy in 2009. Tr. 498. He has been involved in three or four investigations surrounding prescriptions. Tr. 498. He served as case agent for the current investigation. The first search warrant was executed on February 27, 2018, at the clinic and at the Respondent's residence in Clarksville, Tennessee, where paper records, patient files, financial records and digital evidence from several computers were seized. Tr. 500. The second warrant was served on the Respondent's clinic in Millersville, Tennessee in September, 2018. Tr. 500. SA1 authenticated GX 5 as seized from the Respondent's clinic. Tr. 502–03. SA1 noted that some medical documents provided by UC to the clinic were not found during the searches. Tr. 503–04. SA1 authenticated GX 7 as medical records of M.P. seized from the Respondent's clinic. Tr. 505. SA1 authenticated GX 9, as the medical records of M.W. seized from the Respondent's clinic. Tr. 506. SA1 authenticated GX 11 as medical records of C.F. seized from the Respondent's clinic. Tr. 507. SA1 authenticated GX 13, as the medical records of B.C. seized from Respondent's clinic. Tr. 508. SA1 authenticated GX 15, as the medical records of M.H. seized from the Respondent's clinic. Tr. 509–10. These complete records were supplied to the Government's medical expert, Dr.

*[M] Dr. Kennedy opined that the ''spinal surgery . . . definitely supported being on scheduled medications. [But] [t]hat's not even referenced in the medical record.'' Tr. 328. Accordingly, Dr. Kennedy opined that Respondent failed to document a ''recognized medical indication for the use of the controlled substances, which were prescribed.'' *Id.*

*[N] Dr. Kennedy went on to testify that all of the controlled substances prescribed to the individuals at issue (other than the undercover) were ''dangerous.'' Tr. 352. He stated, ''[c]ontrolled substances are dangerous. . . . [In the] context that we're talking about, because of the abnormal drug screens that were essentially ignored, and the documentation about the patient's status was not done. In the face of sometimes very alarming patient red flags, I would say that it was clearly dangerous.'' *Id.* Dr. Kennedy further opines, ''none of the medical records are credible and . . . maintaining a patient on scheduled medications . . . sometimes at high dosages, without having honest, accurate, complete medical records is dangerous.'' Tr. 352–53. This is because, according to Dr. Kennedy, ''those medical records will instruct other people who look at them as to what the motivation was for the treatment . . . [a]nd if what is documented in the medical record simply doesn't made sense or is something that is in conflict . . . [t]hat can . . . present a dangerous situation.'' Tr. 353.

Kennedy. Tr. 511–12. Additionally supplied to the expert were PDMP reports, the missing records supplied to the clinic by UC and the video of the undercover encounters. Tr. 512.

DEA Diversion Investigator (DI)

DI is a Diversion Investigator with the Drug Enforcement Administration. Tr. 519–20. She has been with DEA for ten years. She has been involved in 15–20 investigations involving physicians prescribing controlled substances. As part of the current investigation, she collected relevant prescriptions, and processed the documents in support of the Order to Show Cause. Tr. 520. She identified the Respondent's DEA Registration. GX 1. She authenticated GX 18, which include the prescriptions the Respondent issued to UC, which she obtained from various pharmacies. Tr. 521–22. She authenticated GX 19, which are the prescriptions the Respondent issued to M.H., which DI obtained from various pharmacies. Tr. 523–24. She authenticated GX 20, which are the prescriptions the Respondent issued to C.F., which DI obtained from various pharmacies. Tr. 524–25. She authenticated GX 21, which are the prescriptions the Respondent issued to M.P., which DI obtained from various pharmacies. Tr. 526. She authenticated GX 22, which are the prescriptions the Respondent issued to B.C., which DI obtained from various pharmacies. Tr. 527. She authenticated GX 23, which are the prescriptions the Respondent issued to M.W., which DI obtained from various pharmacies. Tr. 528. She authenticated the Respondent's application for renewal of his DEA Registration for the State of Tennessee, # 59889, which was submitted on November 6, 2019. Tr. 529–30; GX 26.

She explained the significance of Question Three on the application, a ''liability'' question. It queries whether the applicant has ever surrendered for cause, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or have any such action pending. Tr. 530–31. An affirmative answer to Question Three would trigger an investigation by a diversion investigator whether to issue the registration or to deny it. The Respondent answered ''No'' to Question Three. Tr. 531; GX 26.

She also authenticated GX 29, the State of Tennessee Department of Health, Notice of Charges and Memorandum for Assessment of Civil Penalties. Tr. 531–32. She also authenticated GX 27, an order from the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part 3, reversing Denial of Stay, but Accompanying Stay with Conditions. Tr. 532–33. DI noted that as of May 2019, the Conditions preclude the Respondent from writing prescriptions or providing direct patient care during the pendency of the stay. Tr. 533–34. DI authenticated GX 28, An Agreed Order with the State of Tennessee, in which the Respondent was required to surrender his Pain Management Certificate, a professional license, in 2018, and prior to his application for registration in 2019. Tr. 534–35; GX 26; GX 28. DI authenticated GX 25, an Emergency Order of Restriction from the Commonwealth of Kentucky board of License, issued on January 15, 2019, which again predates his subject DEA application, and is a further restriction on a professional license. Tr. 537–39.[28] DI explained that although GX 28 related to the surrender of the pain clinic license and GX 26 was the Respondent's personal application, as the Respondent applied for the pain clinic license himself, it constitutes a surrender of his license, warranting an affirmative response to question 3 of his DEA application. Tr. 542–43; GX 26. Additionally, the surrender is signed by the Respondent individually. Tr. 545.

Respondent's Case-in-Chief

The Respondent presented his case-in-chief through the testimony of one witness, the Respondent, Samson K. Orusa, M.D.

Samson K. Orusa, M.D.

Dr. Orusa was born in Bayelsa, Nigeria. Tr. 547. Dr. Orusa finished his medical education at a fully accredited medical school in Benin City, Nigeria and worked for a year in Nigeria. Tr. 548. He completed a one-year rotational internship in internal medicine, pediatrics, surgery and OBGYN at the University of Port-Harcourt Teaching Hospital. Tr. 549–50. He then spent a year doing outpatient care at a rural primary healthcare center. Thereafter, he entered private practice in Lagos, Nigeria in 1989. In 1992, Dr. Orusa immigrated to the United States to advance his medical training. He completed a three-year residency program in internal medicine at Columbia University, College of Physicians and Surgeons in 1996. Tr. 551. He obtained his Tennessee medical license, and with his certification in internal medicine, he was hired at a clinic in Clarksville, Tennessee. Tr. 552, 555. He was admitted to practice at Memorial Hospital. In 1997, he opened his own clinic in Clarksville, where he had a general medical practice. In 2004, he began concentrating on pain management. Tr. 553. In 2017, he was board certified by the American Board of Interventional Pain Physicians as a specialist in interventional pain medicine. Tr. 553, 555. His extensive training involved the use of deep injections, spinal nerve blocks, nerve injections, foraminal blocks, and epidural injections. Tr. 553–54. By 2018, he held sufficient certification to operate his own pain clinic in Tennessee. Tr. 555.

From 1998 to 2017, the clinic transitioned from primary care to pain management, but even by 2017, he still had primary care patients. Tr. 557–58. Initial visits required appointment, which were scheduled for the first thing in the morning. Returning pain patients were permitted to walk in without appointments. Tr. 558. He has had a staff of ten, including a nurse practitioner and physician's assistant. Tr. 559. By 2017, his pain management practice included deep tissue injections, cervical, lumbar and thoracic nerve blocks, sacroiliac joint injections, and bursitis injections. Tr. 60. In 2018, the frequency of injections increased as the Respondent began performing injections under fluoroscopy. Tr. 560.

The Respondent had a protocol for new pain patients. Tr. 561. Some of these protocols were in writing, but not produced at the hearing. Tr. 620. They were required to bring a referral letter or letter of dismissal from their previous physician, any imaging reports, records from their last three medical visits and their pain medication. Tr. 561–62, 572. If the patient did not produce the materials, the clinic staff would attempt to obtain them. Tr. 564–66. The initial visit typically takes all day, as the patient must fill out extensive documentation (twenty pages with 252 questions), which is necessary for diagnosis and selection of treatment. Tr. 566–67. Seventy-five questions relate strictly to pain. It includes pain disability index, depression assessment, drug-use history and social history. There is a pain management agreement. Tr. 571–72. The staff explains the side effects, the addiction process and the

[28] Although relevant testimony herein, the January 15, 2019 restriction as to the Respondent's Kentucky license does not constitute a ground for the material falsification allegation. It was neither charged in the OSC or the Government's Pre-hearing Statements. Nor was it noticed by the Government at the time of its offering as a proposed additional charge under the principle of ''litigation by consent.'' Where the Government has not provided notice of a particular charge yet produces evidence on that charge, and does not argue that the issue was litigated by consent, the charge cannot form the basis for revocation. *Cove Inc., d/b/a Allwell Pharmacy,* 80 FR 29,037, 29,039 (2015).

resources to help with addiction. Tr. 572.

The charts often contained the exact same language for indications of anxiety and insomnia. Tr. 633–34. The Respondent explained that the language was often identical as anxiety patients typically share the same symptoms. Tr. 634–36.

Undercover

The Respondent took a medical history, a condition-specific physical exam for low back pain, reviewed the MRI (GX 6) of UC. Tr. 575–80. The Respondent noted that his physical exam of UC was not captured by the video of the encounter. The camera was pointed at the wall. Tr. 581–82. The Respondent spent no more than fifteen minutes with UC in the examination room. Tr. 621. The Respondent performed the required assessments related to pain, physical and psychological function, and history and potential for drug abuse. Tr. 582. This involved the paperwork UC filled out, authenticating that paperwork, the triage of UC by staff, UDS, and a final review of the paperwork by the Respondent with the patient. Tr. 583, 584. Although UC's chart contains an entry that his pharmacy printout was reviewed, the Respondent conceded that no pharmacy printout was reviewed and that such entry was in error. Tr. 631–32; GX 5 at 6. UC was a challenge as the clinic he reported had been closed, and he could not obtain the pharmacy information, so the Respondent could not verify that source. Tr. 583–85.

The Respondent expected his patients to be honest and truthful with him, consistent with the DEA Physician's Manual, which requires patients to be honest with their doctors. Tr. 586–87. The Respondent explained that a patient's pain is very subjective. After reviewing his paperwork, including the MRI, examining UC, and speaking with him, the Respondent had no reason not to treat him as someone who had genuine pain. Tr. 588. UC's statement that he had used controlled substances for his pain and that ibuprofen was not working supported the conclusion that his pain was long-standing, and warranted a Schedule II medication. As UC's prior medical records could not be confirmed, the Respondent prescribed a dosage appropriate to a patient just starting opioid treatment. Tr. 589–90. The Respondent testified that he prepared a written treatment plan with appropriate treatment goals and therapy. Tr. 590–91.

The Respondent explained that his electronic medical record often referred to other records. For example under history of present illness (HPI), he would often reference the initial encounter paperwork as included in the electronic record. Tr. 592. He also explained that he performed a physical exam at the initial visit of each of his patients, as required by the Tennessee pain management guidelines. Tr. 594. Physical exams thereafter are at the discretion of the physician. Tr. 594. Although UC had five visits to the clinic, only two involved encounters with the Respondent. The other three visits were ''level one'' visits, in which UC met with the Respondent's staff only. Tr. 622–28, 645–50. Although the medical records reflect a physical examination took place at the level one visits, the Respondent explained that it was permissible in medical record-keeping to carry forward results from prior examinations to later visit records, with new findings added. Tr. 623–28.

Patient M.W.

M.W. was first seen in January 2013. Tr. 595. M.W. was a gunshot victim to whom the Respondent prescribed alprazolam. This was based on the history and physical exam. Tr. 593. Tr. 635–36; GX 9 at 69. The Respondent obtained a medical history, conducted a physical exam, performed an adequate pain, physical, and psychological assessment, history and potential for substance abuse. Tr. 596. The evaluation of the patient's potential for drug abuse is an ongoing evaluation with UDS, involving both office screens, confirmatory lab screens, and pill counts. Tr. 596–98, 600. Once an inconsistent UDS is discovered, the Respondent initiates a dismissal process. Tr. 598–600. The Tennessee pain management guidelines leave it to the physician's discretion on the handling of confirmed inconsistent UDS results. Tr. 598–99. The Respondent gives the patient a month to come into compliance. Tr. 600. If he has a consistent UDS within the month, the patient is permitted to remain in treatment. Tr. 601. The Respondent was able to bring M.W. back into compliance through counseling; however, the chart only documents that the patient was counseled as to the inconsistent UDS. Tr. 637–38. The Respondent prepared a written treatment plan. Tr. 601.

Patient C.F.

Patient C.F. had a stab wound to the chest, requiring heart surgery, resulting in residual chronic pain. Tr. 601. The Respondent took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse. Tr. 601–02. The Respondent noted that he had the benefit of confirmatory records from Vanderbilt University Medical Center. Tr. 602. The Respondent explained that the MED prescribed to C.F. was a relatively low dose of 82.5, noting the 120 MED threshold in which primary care physicians in Tennessee must consult with pain management specialists. Tr. 603–05.

Patient B.C.

Patient B.C. was referred from jail on December 19, 2012. The Respondent noted the pain management guidelines have changed since then. Tr. 605. The Respondent explained why he kept pharmacy printouts in his records because they are easier and quicker to obtain than medical records. Tr. 606. The pharmacy printout informs how long the patient has been prescribed medications, changes in dosage, and the prescriber. Tr. 607. Each of the Respondent's patient records contained the instruction, ''rule out doctor shopping,'' which was a prompt to review the Tennessee PDMP to determine if the patient was obtaining controlled substances from multiple physicians. Tr. 608.

The Respondent took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated his history and potential for substance abuse, and prepared a written treatment plan. Tr. 608. Although the Respondent described the extensive forms each patient is required to fill out at the initial visit, some of the described forms, which were referenced in B.C.'s chart, were missing from the Respondent's records as relates to B.C. Tr. 628–29; GX 13 at 5. The Respondent explained that some records were lost in 2014. Tr. 630. The missing records were not recreated as B.C. was a long-term patient. Tr. 630.

Patient M.H.

Patient M.H. presented with a post gunshot wound to the abdomen and chronic low back pain secondary to degenerative disc disease. Tr. 608. He had already been treated for pain management. He had a history of extensive spinal surgery at Vanderbilt University Medical Center, including a laminectomy. Tr. 609–11. The Respondent prescribed a lower MME than the surgeon prescribed post-operative at Vanderbilt. Tr. 611. The Respondent's medical findings as to Patient M.H. for the visit just prior to M.H.'s major back surgery are the same as the Respondent's findings for the visit the day after the surgery. Tr. 637–38; GX 15 at 48–50. The Respondent

explained that the subject findings were based on history. Tr. 638.

The chart reports M.H. has been ''compliant,'' however, on the next page of the chart, it reports M.H. had an inconsistent UDS. Tr. 638–40; GX 15 at 48–49. The Respondent explained that the inconsistent UDS related to the point of care test, not the confirmatory lab test, so the chart was accurate. Tr. 640. M.H.'s chart contains apparently inconsistent findings of long-term insomnia, but with an entry of sleeping well. Tr. 640–41; GX 15 at 47–48. The Respondent conceded these were inconsistent entries. Tr. 641.

Patient M.P.

Patient M.P. was being managed for chronic pain. In her initial visit, she reported conflicting information regarding whether she had been in drug rehab treatment. Tr. 641–42; GX 7. The Respondent explained that he could only rely on the information provided. Tr. 642. Initially, in September of 2016, the Respondent requested dismissal records, an X-ray and an MRI from Dr. M. Tr. 642–44; GX 7 at 48. Yet, eighteen months later, the Respondent still had not received the requested records. Tr. 644; GX 7 at 59.

Ultimately, she came to the clinic overdosing on heroin. Tr. 611–12. She had to be resuscitated until EMS was able to reverse the effects of heroin with Narcan. Tr. 612. In the post-overdose notes the Respondent took an extensive history again regarding her drug use. He directed she cannot be on pain management but must be on opioid abuse treatment. So, the Respondent started her on Suboxone. Tr. 613. The Respondent explained his understanding of Suboxone induction. The first type of induction therapy is by observation. You give the patient Suboxone and observe them until they reach the point of withdrawal. The other form of induction is to give the patient Suboxone and send her home without observation by the physician. Tr. 612–14. M.P. was initially receptive to drug treatment, but later changed clinics. Tr. 615.

The Respondent took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse, and prepared a written treatment plan. Tr. 615–17. Following the heroin overdose, the determination was made that she needed treatment of Suboxone and no further opioid prescriptions. Tr. 616.

The Facts

Stipulations of Fact

The Government and the Respondent have agreed to 1, 2 in part, 3, 4, 5, 6, 7 stipulations, which I recommend be accepted as fact in these proceedings:

1. The Respondent is registered with the DEA as a Practitioner authorized to handle controlled substances in Scheduled II–V under DEA COR No. BO4959889 at 261 Stonecrossing Drive, Clarksville, Tennessee 37042. DEA COR. No. B04959889 expires by its terms in December 31, 2019.*O

2. On July 6, 2018, the Respondent submitted an application (No. W18070589C) for a new DEA COR at 316 Pappy Drive, Oak Grove, Kentucky 42262. On January 15, 2019, the Commonwealth of Kentucky, Board of Medical Licensure, issued an Emergency Order of Restriction prohibiting Respondent from ''prescribing, dispensing, or otherwise professionally utilizing controlled substances.'' *See* 201 KY. ADMIN. REGS 9:240 Section 1 and 3. Thus the Respondent is currently without authority to handle controlled substances in the Commonwealth of Kentucky.

3. Soma is a brand name of carisoprodol, a Schedule IV controlled substance.

4. Percocet is a brand name for oxycodone, a Schedule II controlled substance.

5. Oxycodone is a Schedule II controlled substance.

6. Oxymorphone is a Schedule II controlled substance.

7. Alprazolam is a Schedule IV controlled substance.

Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

The Government's case was largely based on (1) several undercover visits to Respondent's medical office by UC; (2) the medical charts and prescriptions pertaining to UC as well as to five other patients, M.H., M.W., C.F., B.C. and M.P.; and (3) the testimony of Gene Kennedy, M.D., the Government's expert.

The Undercover Operation

1. UC is currently an Assistant Special Agent in Charge with the Tennessee Bureau of Investigation. Tr. 30. [Omitted to preserve identity of UC.]

2. UC testified that he was contacted by a Special Agent with the United States Department of Health and Human Services, Office of the Inspector General, to conduct an undercover operation at Respondent's clinic. Tr. 33–34. In preparation for this operation, UC contacted Respondent's clinic to set up an appointment. Tr. 34. He was told to bring several items to the appointment, including an MRI report, prior ''chart notes'' from his previous physician, a discharge summary from his previous physician, and documentation showing his last three months of prescriptions. Tr. 35.

October 3, 2017 Visit

3. UC testified he arrived at Respondent's office on October 3, 2017, at approximately 8:00 a.m. Tr. 40. He testified that he paid $311 for this appointment. Tr. 49. He recorded portions of the visit on a ''covert video camera device embedded'' in a cell phone case. Tr. 42–43. Upon arrival, he provided an MRI report from September 2, 2016, that he testified was ''authentic in the sense that it was my physical MRI.'' However, the physician's name on the report had been altered. Tr. 35, 37; GX 6 at 8–9. UC also provided ''fabricated'' medical records which appeared to be signed by a nurse practitioner in Missouri. This nurse practitioner, according to UC, was no longer practicing in October 2017. Tr. 37–8; GX 6 at 10–11. UC did not provide a discharge summary or any prescription information. Tr. 39–40; 133. Nor did he provide any documents to show he had undergone a prior physical examination. Tr. 133.

4. After providing the materials, UC was given what he estimated to be approximately twenty pages of paperwork to fill out, none of which was included in his medical file seized later by DEA. Tr. 40; GX 5. However, UC took photographs of the forms before turning them in. Tr. 100. When asked to state his pain level, UC testified he told the clinic staff that it was ''9'' out of ''10'' (''9/10''), but when he was examined, he exhibited no overt indications of pain. Tr. 47, 56. 95. In fact, on one of the forms, he listed his quality of life as nine out of ten. Tr. 131–32. On another form, he rated his pain disability as only two out of ten. Tr. 132. On one form, he also denied he suffered from insomnia, Tr. 132–33, but wrote on another form that he sought to work without pain and sleep through the night. Tr. 135. No one questioned him about these contradictions. Tr. 139. UC acknowledged that he filled out

*O According to Agency records, this application is pending renewal and has not expired.

forms at his first appointment on October 3, 2017, and took photographs of the forms. Tr. 100. The completed documents, however, were not part of the Respondent's medical file seized by DEA and were not offered as exhibits by either party. Tr. 100; GX 5.

5. UC testified that one of the Respondent's employees apparently questioned the authenticity of the records he provided, stating that people are trying to ''bring down Dr. Orusa.'' Tr. 41–42. This employee was not named, but was identified as the person depicted in GX 30. UC testified that, after providing the paperwork, his vital signs were recorded, including his blood pressure. He was also asked about his weight and asked to give a urine sample. Tr. 44–45.

6. UC described the October 3, 2017 visit as follows. He testified that he made no attempt to demonstrate that he had a disability. He did not limp or change his gait. Tr. 45–46. Though UC arrived at the clinic at approximately 8:00 a.m., he did not meet with Respondent until approximately 4:00 p.m. Tr. 47–48. During UC's encounter with Respondent, UC informed Respondent that the last ''pain clinic'' he visited was ''Dr. Chapman in Pierce, City, Missouri, and had recently ''closed down.'' GX 4 at 1. He also told Respondent that the person who ordered his MRI was ''Dr. Morgan,'' a fictitious person. Tr. 37; GX 4 at 2. There was also a discussion about UC providing ''pharmacy information.'' GX 4 at 3. UC told Respondent he would ''get those records if I need to'' but did not know the pharmacy's phone number.

7. UC testified that he did not produce any additional records. Tr. 55. UC testified that, during his meeting with Respondent, he saw Respondent ''going through some forms on the counter,'' but could not determine what Respondent was reviewing. Tr. 105. UC testified that he told Respondent he fell while unloading a truck in 2013. Tr. 117; GX at 1. He told Respondent that he was managing his pain with over-the-counter medications. Tr. 104. Though he told Respondent that he could ''barely function,'' he did not ''elaborate'' and there was no further discussion about this statement. Tr. 124; GX at 2; GX 17. UC testified that, in response to Respondent's question about a previous diagnosis, he told Respondent that a previous medical provider told him he had degeneration of some sort and ''some arthritis.'' Tr. 105–06; GX at 1.

8. UC testified that Respondent performed a cursory physical exam described as ''less than 60 seconds of any kind of physical touching.'' Tr. 56. He testified that Respondent instructed him to remain seated and UC ''just told [Respondent] where the pain was. If he did something and asked me if it hurt I would respond that I felt pain in that area.'' Tr. 56. He testified that he made no ''faces'' and did not ''wince'' when touched. Following the exam, Respondent inquired about UC's past pharmacy records. UC told Respondent. ''I'll get those records if I need to.'' Tr. 108–09; GX at 3. UC testified that Respondent wanted to do ''injections,'' but UC refused. Tr. 117. According to the transcript of the meeting, UC told Respondent that he hated needles. GX at 3.

9. Approximately 30 minutes after he left the exam room, UC received a prescription for 42 tablets of 10 mg oxycodone, even though he never asked for oxycodone. GX 18 at 1; Tr. 57. During the encounter with Respondent, UC said that he had previously been given hydrocodone, Xanax (alprazolam) and ''oxys.'' GX 4 at 2. He also told Respondent that he was currently managing his pain with ''Advil this past month'' and had been ''miserable.'' *Id.* UC testified that he also received two other prescriptions for non-controlled substances, including Flexeril (cyclobenzaprine) and meloxicam. Tr. 58.

10. When asked why, he told Respondent he had lower back pain as opposed to pain in some other area, UC testified that, due to his exercise schedule, which including running five to seven miles each day, a practitioner might find objective evidence to justify complaints of knee, ankle, or shoulder pain. Here, he testified, he had ''absolutely no back pain whatsoever.'' Tr. 114–15. He testified that, if Respondent's clinic had been ''doing their job,'' he would ''not expect to walk out with a prescription.'' Tr. 105. Also, in his experience as an undercover operative, he testified that ''more often than not'' he has been refused prescriptions for controlled substances on the first visit. Tr. 123–24.

11. A video recording of UC's meeting with Respondent was played during the hearing. GX 17. UC testified that the video portion was a fair and accurate recording of his ''entire encounter with'' Respondent on October 3, 2017. Tr. 55. UC also testified that the transcript of that encounter (GX 4) was an accurate representation of the recording. Both the recording and the transcript were accepted into the official record. GX 4, 17; Tr. 70–71, 187–88.

October 17, 2017 Visit

12. UC testified that, in order to receive more ''narcotic prescriptions,'' he was required to come in for a ''well-care'' visit before making an appointment during which he would receive narcotics. Tr. 57–58. On October 17, 2017, he returned to the clinic and paid $25 for the visit. Tr. 57–59; GX 4, GX 17. He was then called back to a ''triage room'' and asked about his weight and blood pressure. Tr. 59.*P He saw the Respondent for ''about one minute,'' during which Respondent asked him if he slept well. When he responded, ''not really,'' Respondent wrote him a prescription for amitriptyline. Tr. 59; GX at 4. This encounter was also recorded. GX 17. UC testified that, during this visit, no physical exam was performed. Tr. 71–72. He testified that no one examined his lower back, extremities, or checked his muscles. Tr. 72.

October 18, 2017 Visit

13. UC testified that, on October 18, 2017, he returned to the clinic for refills of narcotic medications. Tr. 74. Because the clinic would no longer accept cash, he secured a debit card to pay for the appointment, which cost $377. Tr. 75–76. During the October 18, 2017 appointment, UC waited approximately two and a half hours. He was not examined and he met with medical personnel only for the purpose of paying the fee and receiving his prescription. There was no discussion about his medical condition and he provided no medical records. Tr. 76–77. At the end of this visit, he received a prescription for 84 tablets of 10 mg oxycodone, twice as much as he received 15 days earlier. Tr. 78; GX 18 at 3–4.

November 15, 2017 Visit

14. UC testified that, on November 15, 2017, he returned to the clinic for a fourth time. On this visit, he testified that he paid $25, ''waited for some amount of time,'' was ''asked'' about his weight and blood pressure, and was dismissed. Tr. 83–84.

November 20, 2017

15. UC testified that, on November 20, 2017, he returned to the clinic for a fifth time. He described this as a ''medication visit.'' Tr. 87. UC testified that, during this visit, he wrote down his name on

*P This section of the Recommended Decision included several superscript numbers in the body of the text without any corresponding text in footnotes. As I believe that the superscript text was likely the result of a scrivener's error, I have deleted them throughout this section without further demarcation.

a clipboard, ''paid a certain amount of money,'' and waited a ''certain amount of time'' before he was given his prescriptions. Tr. 87–8. UC testified that he was asked to provide a urine sample to which he added ''a vial of a substance that would cause me to test positive for oxycodone.'' Tr. 88. At this visit, he received another prescription for 84 tablets of 10 mg oxycodone. GX 18 at 4; Tr. 89.

Falsified Medical Records

16. UC identified numerous entries in his medical record that indicated his medical chart had been fabricated. For instance, on October 17, 2017, Respondent wrote that UC exhibited a number of ''[a]nxiety symptoms'' such as shortness of breath, ''palpitations, sweating, dizziness, [and] shaking.'' GX 5 at 5. UC testified that he never reported any of these symptoms. Tr. 79–80. Respondent also wrote that UC reported ''no headache, no dizziness, no nausea, no vomiting, no abdominal pain, no diarrhea, no constipation, no [shortness of breath], no chest pain, [and] no palpitations.'' GX 5 at 5. UC testified that he was never asked about any of these symptoms. Tr. 80–81. UC was also asked about a notation for October 17, 2017, where his weight and blood pressure were recorded. GX 5 at 5. He testified that he was neither weighed, nor did anyone measure his blood pressure on that day. Also, on October 17, 2017, Respondent wrote ''Chest: no deformities, no asymmetry, no rales, no wheezes, normal vesicular breath sounds.'' GX 5 at 5. UC testified that no one ever examined his chest or evaluated his breathing. Tr. 81–82.

17. Regarding the medical records for October 18, 2017, Respondent's entries for this appointment were identical to those made the day before. Again, he wrote ''ROS for MSS is positive for muscle pain, back pain, joint pain, and body aches and pain.'' GX 5 at 4. Respondent again repeated the same notations about UC's chest and breathing. However, all of this was created on a day when UC did not see the Respondent. Nor was UC examined by anyone else at the clinic that day. Tr. 82–83.

18. With respect to the November 15, 2017 visit, Respondent repeated the same notations even though, as UC testified, no exams were performed and Respondent was not there to see him. Nevertheless, Respondent wrote out a list of symptoms in the section marked ''HPI,'' GX 5 at 4, which correspond to the visit on November 15, 2017. Again, UC testified that none of these symptoms were ever discussed and no examination was performed. Tr. 86. Likewise, with respect to Respondent's notes in the section marked ''PE'' (physical exam),'' UC testified that no one examined his chest or breathing. Tr. 86–87.

19. Finally, regarding the November 20, 2017 visit, Respondent wrote, as he had four times previously, that UC was ''positive for muscle pain, back pain, joint pain and body aches.'' GX 5 at 3. UC testified that no physical exam was performed on this day. Tr. 90–91. Respondent also, for the fifth time, described a physical examination (section ''PE'') that was never performed. GX 5 at 3; Tr. 91.

20. UC also testified about the results of his urine drug screening. He noted that, despite adding an oxycodone solution to his urine on November 20, 2017, his records showed ''UDS ALL NEG.'' Tr. 91–92; GX 5 at 3. UC also testified that there was no discussion about this result. Tr. 92.

Expert Review

21. Dr. Kennedy testified as the Government's expert. Dr. Kennedy owns a pain management clinic on St. Simons Island, Georgia; has treated more than 1000 patients, but his current practice involves fewer than 100 patients. Tr. 143–46. He testified that he has treated patients with post-surgical issues, patients with cancer pain, and patients with back pain. Tr. 178–80. Most of his patients, he testified, need to have their medications ''managed.'' Tr. 143–44. Dr. Kennedy testified that he has been practicing pain management for approximately 15 years. Tr. 145, 179–80. He is licensed to practice medicine in Georgia and runs a ''state licensed pain management clinic.'' Tr. 146; GX 24. Dr. Kennedy is not board certified. Tr. 373.

22. Dr. Kennedy testified that, in his practice, he prescribes controlled substances, including opioids such as oxycodone and hydrocodone. Tr. 181. He has treated insomnia and/or anxiety with benzodiazepines, such as lorazepam, diazepam, and alprazolam. Tr. 181–82. He has also prescribed muscle relaxants such as carisoprodol. Tr. 181–82.

23. Dr. Kennedy has also lectured on controlled substances ''numerous times'' at the DEA training facility in Quantico. He has taught at the National Advocacy Center, and at various DEA and Department of Justice (''DOJ'') ''venues'' around the country. Tr. 184–85. He also taught a course for pharmacists in Tennessee. Tr. 185.

24. Dr. Kennedy testified he has served as an expert witness in numerous cases, including those involving physicians alleged to have improperly prescribed controlled substances. Tr. 182. He estimates he has testified 13–14 times. *Id.*

25. As the Government's expert, Dr. Kennedy reviewed the medical charts for patients UC (GX 5), M.P. (GX 7), M.W. (GX 9), C.F. (GX 11), B.C. (GX 13), and M.W. (GX 15). He also reviewed the prescriptions for these patients (GX 18–23), the undercover video created by UC, the transcripts (GX 17 and 4) of that video, and UC's reports of his undercover visits (GX 3). Tr. 183–84, 186–89; 213–16.

26. Dr. Kennedy explained that, according to the minimal standard of care for prescribing controlled substances in Tennessee, a physician must: (1) Take an adequate medical history; (2) perform a physical examination; (3) obtain past medical records; (4) order diagnostic testing if indicated; [and (5) maintain complete and accurate medical records.] Tr. 189–90, 195–96, 353.

27. Dr. Kennedy testified that, according to the minimal standard of care, a physician's medical records should contain the following; (1) past medical records or attempts to obtain past medical records; (2) a ''pain history'' or ''collection of statements pertaining directly'' to the patient's pain history; (3) history of ''drug abuse, chemical dependency, [or] alcoholism;'' (4) records of a physical examination ''that is specific and pertinent to the problem;'' (5) patient assessment; (6) treatment plan; and (7) efforts to obtain state pharmacy reports. Tr. 197. He also testified he was familiar with Tennessee regulations requiring a physician to keep accurate and complete medical records. Tr. 201.

28. Dr. Kennedy testified that, in cases where physicians prescribe opioids in combination with benzodiazepines, a physician must have a ''heightened sense of vigilance managing the patient'' and this should be noted in the medical record. Tr. 190–91.

29. Dr. Kennedy testified that there are indications of possible drug abuse and/or diversion in patients whose medical histories are ''difficult to obtain'' as well as patients with ''cloudy histories of drug abuse.'' Tr. 191–92. He discussed urine drug screening (''UDS'') and how a physician must respond if a patient's UDS result shows an ''abnormality, it's not simply enough to just to say a patient's urine is positive for cocaine or positive for methamphetamine. The physician also has an obligation to say that the patient is positive for this substance, and I discussed it with the patient, and I'm going to do this if it happens again or I'm going to adjust the medications or

not adjust the medications. And it has to be something that is utilized as a diagnostic treatment.'' Tr. 194. Dr. Kennedy further testified that the above information should be documented in the medical record. *Id.*

30. Dr. Kennedy testified that, prior to testifying in this matter, he reviewed Tennessee regulations pertaining to the prescribing of controlled substances. He confirmed that these regulations included requirements that a physician must (1) take the patient's documented medical history; (2) perform a physical examination; (3) perform an adequate assessment and consideration of the patient's pain, physical, and psychological function: And (4) take a history for the potential of substance abuse.*Q Tr. 200. Dr. Kennedy also testified that he was familiar with rules prohibiting a physician from prescribing controlled substances to a person addicted to the habit of using controlled substances without making a bona fide effort to the cure the patient's habit. Tr. 199.

31. Based on his qualifications and expertise, his knowledge of Tennessee regulations and statutes, and his experience as an operator of a pain management clinic, Dr. Kennedy was accepted as an expert in pain management qualified to give an expert opinion regarding Respondent's prescribing of controlled substances. Tr. 211–12; 216.

Undercover

32. With respect to the undercover officer, Dr. Kennedy testified he reviewed the video recording UC made during his visits to Respondent's clinic on October 3 and October 17 of 2017 (GX 17); UC's investigative reports for all five of his visits to Respondent's clinic; the patient medical file pertaining to patient UC; and the prescriptions issued to UC by the Respondent. GX 3, 5, 17–18; Tr. 184–86, 216, 239.

33. Dr. Kennedy testified that, based on his review, UC was being treated for back pain. He testified that the physical exam was inadequate, describing it as ''cursory in that it consisted of essentially observing'' UC, ''touching his back, and having him lift his leg once.'' Tr. 217. Dr. Kennedy testified that a minimally adequate exam would include ''observing the patient's back, looking for muscle spasms, performing ''lumbar range of motion maneuvers where the patient . . . bends at the waist in various directions,'' doing a neurologic exam, and doing a ''straight leg raised test having the patient laying supine on the table.'' Tr. 224–25. Dr. Kennedy concluded that, based on the medical records, there were no ''positive findings on physical examination.'' Tr. 226. In other words, he testified, Respondent's ''physical exam findings'' failed to support a ''pain ideology'' and certainly could not justify a reported pain level of 9/10. Tr. 226–27, 234. With respect to the Respondent's diagnosis (GX 5 at 2) of ''[d]egeneration of [l]umbar [i]ntervertebral [d]isc . . . [l[umbar [s]pondylosis . . ., and [i]nsomnia,'' Dr. Kennedy noted that even the MRI failed to mention degenerative disc disease and Dr. Kennedy could identify no other findings to justify that diagnosis. Tr. 240–42. And though spondylosis could be severe enough to ''be causing symptoms,'' Dr. Kennedy testified that there was no evidence that these symptoms existed. Tr. 242. Dr. Kennedy also testified that neither UC's MRI report, nor the prior medical records, justified the prescribing of controlled substances. Tr. 228, 230.

34. Looking at Respondent's medical record for patient UC, Dr. Kennedy further concluded that the record was rife with fabrications as the following testimony indicates: ''. . . if you look it says on the second line, chest, no deformities, no asymmetry. The only way to determine [this] is to look at them with their shirt off. And this patient was not required to disrobe . . . there is also no indication . . . that the heart and lungs were evaluated. But there are heart and lung evaluations as well as the chest appearance . . . . you couldn't see everything, but clearly listening to the audio, I didn't hear any breathe in, breathe out, anything that would indicate to me that there was a physical exam that included these things.'' Tr. 218–19. Dr. Kennedy further noted that the description of UC's general exam in the section marked ''PE'' (GX 5 at 6) was not only inaccurate, but was identical to language he found in more than 20 medical charts he reviewed for other patients. Likewise, Dr. Kennedy disputed the truth of the information supposedly used to support a finding that UC suffered from insomnia. Tr. 233. This was further confirmed by UC's testimony, in which he testified that he neither reported nor manifested any of the listed ''insomnia'' symptoms. Tr. 79–80, 134–35, 139. Dr. Kennedy also testified that the physical exam depicted in the video (GX 17) as well as UC's subsequent encounters could not possibly support the repeated findings corresponding to visits on October 17 and 18, as well as the visits on November 15 and 20. GX 5 at 3–5; Tr. 235–37.

35. Dr. Kennedy testified that UC, as an undercover patient, also manifested various ''red flags'' for possible drug abuse and/or diversion. Tr. 230. He noted that UC's prior medical records showed only a ''single office visit'' (GX 6 at 10) from a provider in another state and documentation from the encounter showed a ''completely normal physical exam with no positive findings at all.'' Tr. 220–31. Dr. Kennedy testified that a patient who comes from a clinic that has closed and provides medical records from a practitioner whose license has been suspended are red flags for diversion. He further noted that none of these red flags was ''significantly'' addressed by Respondent prior to prescribing oxycodone. Tr. 238.

36. In summary, Dr. Kennedy testified that, with respect to UC, Respondent: (1) Failed to discuss the risks and benefits of the use of oxycodone; (2) failed to maintain truthful and accurate medical records; (3) failed to assess the patient's pain, physical and psychological function; (4) failed to assess the patient's history and potential for substance abuse; (5) failed to assess any co-existing diseases, conditions in the presence of a recognized medical indication for the use of oxycodone; and (6) failed to create and follow a legitimate written treatment plan for the patient's individual needs. Tr. 231–32, 237–38. Dr. Kennedy further concluded that Respondent's prescribing of controlled substances to UC was outside the usual course of professional practice. Tr. 239. Additionally, Dr. Kennedy concluded that the prescriptions issued to UC lacked a medical justification. Tr. 239; *see also* GX 6 (Dr. Kennedy's expert report on patient UC), 18 (prescriptions issued to UC).

Patient M.W.

37. Dr. Kennedy testified that Respondent treated M.W. for lower back and limb pain. Tr. 245. M.W. was prescribed alprazolam, carisoprodol (Soma), oxycodone, and oxymorphone. GX 23. In his review, Dr. Kennedy stated that there was nothing that meaningfully supported a chronic pain condition. *Id.* Dr. Kennedy discussed a form in M.W.'s file titled ''Pain Management Physical Exam.'' (GX 9 at 14/GE 10 at 7). He testified that the form

*Q I find that Dr. Kennedy credibly testified that the applicable standard of care in Tennessee is as described in Finding of Fact Nos. 26–27 *supra*. The requirements of the Tennessee regulations are clearly components of and incorporated into the standard of care set forth by Dr. Kennedy at Finding of Fact Nos. 26–27. TENN. COMP. R. & REGS. 0880–02–.14(6)(e)(3)(i). Further, Dr. Kennedy's expert testimony is unrebutted in this proceeding.

indicated only ''normal findings'' and ''acute findings.'' Tr. 247. Yet, the patient reported a pain level of 10/10. Tr. 248–49; GX 9 at 19; GX 10 at 8. As Dr. Kennedy testified, in order to support such a high pain level, there would have to be ''very, very significant findings on lumbar exam.'' For instance, he testified, he would not expect to see a patient whose ''gait is normal.'' Tr. 250. Dr. Kennedy also testified that it would be unusual to see a 25 year old patient with degenerative disc disease. In that case, he testified, he would expect Respondent to order radiologic studies to confirm the diagnosis. Tr. 262–63; GX 10.

38. Dr. Kennedy also found nothing in M.W.'s medical chart to justify the continuing prescribing of alprazolam. Tr. 260–62. Rather, he found ''identical language [to] that [which] was used to diagnose insomnia'' for UC. Tr. 261; *see also* GX 9 at 84 (''HPI'' entry); *compare to* GX 5 at 5 (same). There was no evidence, Dr. Kennedy testified, that M.W. suffered from insomnia. Tr. 264.

39. Dr. Kennedy also testified that there were numerous red flags in M.W.'s medical chart for abuse and/or diversion. Specifically, M.W.'s chart showed a ''wildly abnormal'' drug screen in which M.W. tested positive for morphine, hydromorphone, and THC in March 2016. He was also negative for carisoprodol and alprazolam, two drugs he was being prescribed and was supposed to be taking. Tr. 251–52; GX 9 at 2–4. Based on the medical record, Dr. Kennedy testified that this abnormal result was not ''meaningfully addressed.'' Tr. 252. Elsewhere in the chart, there were other examples of abnormal drug screens. On March 28, 2016, Respondent wrote ''UDS pos for oxy-unsat.'' GX 9 at 102. Then, according to an UDS lab report dated May 11, 2017, M.W. tested negative for four controlled substances he had been prescribed, including oxycodone, oxymorphone, alprazolam, and carisoprodol (Soma). GX 9 at 10. Inexplicably, six days before M.W. provided the specimen, Respondent wrote that M.W. was negative for all prescribed drugs. GX 9 at 85. On May 31, 2017, Respondent wrote that M.W. is ''dismissed'' with ''one month notice,'' but noted *on the same day* that M.W. was ''compliant and consistent.'' GX 9 at 83–84. However, less than a month later, the ''dismissal [was] reversed.'' GX 9 at 83. Dr. Kennedy said, ''[i]f the patient is negative for the medication and its metabolites of essentially everything that's prescribed, there's a problem.'' Tr. 260. Dr. Kennedy testified that this was evidence of drug abuse, which Respondent failed to adequately address. Tr. 265.

40. With respect to M.W.'s medical records, Dr. Kennedy again cited numerous inconsistences that questioned Respondent's credibility. For, instance, he testified that the findings on the handwritten physical exam form (GX 9 at 14) did not match those listed in Respondent's electronic medical record (GX 10 at 9). Instead, Dr. Kennedy found the same language in M.W.'s chart that was present in UC's medical chart and in the charts for other patients he reviewed. Tr. 250–51. Dr. Kennedy noted that, out of 98 different encounters, Respondent repeated the same notes 93 times. Tr. 264. This, he testified, rendered the medical file ''not credible.'' Tr. 251. Dr. Kennedy also cited the fact that Respondent described M.W. as ''compliant and consistent'' the same day he tested negative for all the controlled drugs he was supposed to be taking. Tr. 258–59. Again, he described the inconsistency as ''simply not credible.'' Tr. 259.

41. In summary, Dr. Kennedy testified that, with respect to M.W., Respondent: (1) Failed to perform an adequate physical examination; (2) failed to assess the patient's pain, physical, psychological function; (3) failed to assess the patient's history and potential for substance abuse, coexisting diseases and conditions; and (4) failed to create a legitimate written treatment plan for the patient's individual needs. Tr. 265. He further testified that Respondent failed to maintain a truthful and accurate medical record for M.W. Tr. 265–66. Dr. Kennedy testified that the controlled substances in GX 23 were prescribed to M.W. outside the usual course of professional practice. Tr. 266–68. Lastly, Dr. Kennedy testified that his opinions applied to all the prescriptions in GX 23. Tr. 266.

Patient C.F.

42. Dr. Kennedy testified that patient C.F. was treated for ''chronic pain due to trauma, unspecified inflammatory polyarthropathy.'' Tr. 269. However, he testified that C.F.'s physical examination did not support the controlled substances prescribed. *Id.* Dr. Kennedy noted that, while C.F. had scars, her muscle strength was normal as well as her tendon reflexes, and her fine touch sensation. Also, he testified that C.F.'s ''[l]eg raise tests were normal bilaterally'' and her gait was normal. Tr. 270; GX 11 at 106. Dr. Kennedy also testified that the findings in Respondent's ''Pain Management Physical Exam'' (GX 11 at 106) were not accurately reflected in Respondent's electronic medical record. Tr. 271. Rather, he testified, that portion of Respondent's medical record contained findings ''present in the other charts that we've already discussed.'' Tr. 271–72; GX 11 at 69. Dr. Kennedy also testified that he could find no evidence of any credible follow-up physical exams being performed even though C.F. remained a patient for nearly four years. Tr. 272. Nor did he find any evidence that Respondent ordered any supporting studies. *Id.*

43. Dr. Kennedy testified regarding the long term prescribing of alprazolam to C.F. He testified that there was no justification for this since the objective findings to support a diagnosis of insomnia and/or anxiety were identical to those found in medical records for other patients, including those pertaining to UC. GX 11 at 39; Tr. 286–87.

44. Dr. Kennedy testified he also found evidence of possible abuse/diversion that Respondent never adequately addressed. In GX 11 at 117, a laboratory report dated July 9, 2018, shows that C.F. tested negative for prescribed controlled medications, a result that Respondent himself labeled as ''Unsat.'' GX 11 at 117; Tr. 274. According to Respondent's own records, this test was taken just three days after C.F. was prescribed alprazolam, oxycodone, and oxymorphone. GX 11 at 9; Tr. 274–75. Pursuant to a report dated July 7, 2017, C.F. tested negative for alprazolam and positive for hydrocodone. GX 11 at 111; Tr. 275. On June 30, 2017, Respondent's records showed C.F. was prescribed alprazolam, but hydrocodone is not listed. GX 11 at 25; Tr. 275–76. Dr. Kennedy testified that, according to notes from a subsequent visit on July 26, 2017, the abnormal drug screen result is never mentioned. GX 11 at 23; Tr. 288–89.

45. Additionally, Dr. Kennedy testified that, according to a lab report dated July 13, 2014, C.F. tested positive for a diazepam metabolite, negative for alprazolam, and positive for cocaine, oxycodone, oxymorphone, and THC. GX 11 at 79; Tr. 276–278. However, at the next visit on August 11, 2014, Respondent's medical records made no reference to these abnormal results. GX 11 at 69; Tr. 278–79.

46. Regarding C.F.'s multiple unsatisfactory drug screens, Dr. Kennedy testified that it is insufficient for a physician to simply document that the patient was counseled. Rather, he testified, the doctor needs to document how the abnormalities are ''going to affect treatment.'' Tr. 283–84. Dr. Kennedy testified that ''repeating over and over that the patient was counseled. . . leads to the impression

. . . that it's not making any difference to the prescriptions for schedule medications that are being provided.'' *Id.*

47. Regarding C.F.'s medical record, Dr. Kennedy testified that Respondent's description of his review of systems (''ROS'') was repeated throughout C.F.'s chart and found in numerous other charts. Tr. 272–73. Likewise, the section labeled ''Gen exam'' was repeated 102 times and also found in other charts. Tr. 273. Also, as stated above, Respondent's description of the physical exam failed to reflect the actual handwritten notes but rather mirrored what had been written about other patients, including UC.

48. In summary, regarding patient C.F., Dr. Kennedy testified that Respondent: (1) Failed to take an adequate medical history; (2) failed to perform an adequate physical examination; (3) failed to perform an adequate assessment in consideration of the patient's pain, physical, and psychological function; (4) failed to take an adequate history and evaluate the potential for substance abuse; (5) failed to create a written treatment plan tailored for the individual needs of the patient; (6) failed to consider the patient's pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities, (7) failed to discuss the benefits and risks of the use of controlled substances; (8) failed to conduct a documented periodic review of the care at reasonable intervals in view of the individual circumstances of each patient; (9) failed to keep complete and accurate records of the care provided; and (10) continued to issue prescriptions for controlled substances without making a bona fide effort to cure the patient's habit. Tr. 284–86.

49. Dr. Kennedy further testified that, for the reasons in Finding of Fact no. 48 and given C.F.'s numerous abnormal drug screen results, the issuing of prescriptions for controlled substances to C.F., including those in GX 20, were issued ''outside the scope of acceptable medical practice.'' Tr. 287.

Patient B.C.

50. Dr. Kennedy testified that B.C. was treated for ''chronic pain syndrome.'' Tr. 290. He testified that he found no handwritten notes reflecting a physical exam and that the electronic records showed results that were ''non-supportive'' of a chronic pain condition. Tr. 290–91. Dr. Kennedy explained that the electronic records, in the category of ''systems review,'' reflected 141 encounters with Respondent and the ''system review documentations was repeated 140 times.'' He also testified that the ''physical exam documentation was repeated ''approximately 134 times.'' According to Dr. Kennedy, this same documentation was found, verbatim, in other charts. Tr. 292.

51. Though Dr. Kennedy acknowledged that B.C. seemed to have serious medical ''problems,'' such as Hodgkin's lymphoma, a cancer of the lymphatic system, Respondent's notes, inexplicably, failed to reflect those problems. Dr. Kennedy noted, for instance, that the review of systems for B.C. showed, among other things, that B.C.'s ''endocrine'' was ''negative.'' Tr. 292–93; *see, e.g.,* GX 13 at 169. Dr. Kennedy also took issue with the fact that Respondent, after repeatedly reporting a nonsensical pain level of ''/10'' over the course of nine sequential encounters,'' began to record a pain level of 10/10 without medication and 8/10 with medication. Tr. 295–96. Dr. Kennedy testified that, despite B.C. being dismissed from another physician, there was also no attempt to obtain prior medical records. Tr. 304.

52. Dr. Kennedy testified that there were numerous red flags in B.C.'s chart for abuse and/or diversion. First, B.C. had been dismissed from a previous physician, GX 13 at 188, Tr. 293–94, an issue that was not investigated. Tr. 294. Respondent also noted that B.C. lied about his prescriptions at the first encounter—another issue that does not appear to have been addressed. Tr. 296; GX 13 at 169. In fact, Dr. Kennedy testified that the record, despite evidence of B.C.'s untruthfulness, appears to show that Respondent prescribed controlled substances to B.C. without ordering a UDS screen, something that ''is outside the course of usual medical practice.'' Tr. 297; GX 13 at 169. Dr. Kennedy testified that there were also abnormal drug screen results. On February 20, 2013, B.C. was positive only for oxycodone when he was also prescribed alprazolam. Tr. 298; GX 13 at 166. A note dated March 26, 2013, indicated ''unsatisfactory benzo only UDS.'' Tr. 298–99; GX 13 at 165. On August 19, 2013, B.C. was positive for opioids only, another unsatisfactory result. Tr. 299; GX 13 at 158. Dr. Kennedy identified more abnormal results, including one where B.C. testified positive only for benzodiazepines when he was also being prescribed oxycodone. Tr. 299; GX 13 at 156–57. In another note, B.C. tested positive only for oxycodone when he was also being prescribed alprazolam. GX 13 at 155–65 (October 6, 2014 entry); Tr. 300. On December 22, 2014, Respondent noted that B.C. was negative for all drugs, another unsatisfactory result. Tr. 300–01; GX 13 at 150. And though the record indicates the patient was counseled, Dr. Kennedy testified that there was ''nothing specific about what the counseling entailed or any decisions'' made as a result. Tr. 301.

53. Dr. Kennedy also testified that B.C. had been in jail, another red flag. Tr. 301–02. Dr. Kennedy testified that, in this case, a ''reasonable physician would provide documentation that supports that this was addressed and taken into account in pursuing a treatment plan.'' Tr. 302–03.

54. Dr. Kennedy noted numerous instances where the medical chart, instead of recording an actual pain level, listed a nonsensical pain level of ''/10.'' Tr. 294–95.

55. In summary, Dr. Kennedy testified that Respondent's examination of B.C. did not support a chronic pain condition. He testified that Respondent: (1) Failed to take an adequate medical history; (2) failed to perform a sufficient physical examination; (3) failed to perform an adequate assessment in consideration of the patient's pain, physical and psychological function; (4) failed to take an adequate history for the potential for substance abuse, coexisting diseases and condition; (5) failed to show the presence of a recognized medical indication for the use of a dangerous drug or controlled substance; (6) failed to create a written treatment plan tailored to the individual needs of the patient; (7) failed to adequately address the need for further testing, consultation, referrals or other treatment modalities; (8) failed to discuss the risks and benefits of the use of controlled substances; (9) failed to do a documented periodic review of his care at reasonable intervals in view of the individual circumstances; and (10) failed to keep complete and accurate records of the care provided. Tr. 304–06. Dr. Kennedy testified that, in his view, there was no medical justification for issuing prescriptions for controlled substances to B.C. and, as a result, the prescriptions were issued outside the usual course of professional practice. Tr. 307–08; GX 22.

Patient M.H.

56. Dr. Kennedy testified that M.H. was being treated for ''chronic pain syndrome.'' Tr. 309. He testified that Respondent performed a physical exam; however, the findings were identical to those for other patients. *See* GX 15 at 62–63 (sections marked ''PE'' for February 4, 2015, and April 1, 2015); Tr. 310–11. Moreover, Dr. Kennedy testified that these findings did not support a chronic pain condition and that the

treatment was ''outside the scope of acceptable medical practice.'' Tr. 311–12. Dr. Kennedy also testified about an ''extremely'' unusual situation in which M.H. underwent extensive spinal surgery and was discharged from the hospital on October 4, 2016. However, the medical chart entry dated October 5, 2016, shows no mention of the surgery and no evidence that a physical exam was performed. Tr. 320–22, 323–24; GX 15 at 26 (hospital notes), at 48 (encounter note for October 5, 2016). Dr. Kennedy described the situation as follows: ''this whole thing is about scheduled medications to begin with. This is ostensibly a chronic pain patient. He has been discharged from the hospital the day before this encounter after having had a major, major spinal surgery. And not only it is not mentioned in this encounter note, but essentially this encounter note is normal and identical to all the other encounter notes.'' Tr. 322–23. Dr. Kennedy also found no justification for the continued prescribing of alprazolam. As with the other patients, the factual findings related to insomnia/anxiety were identical to the findings found in charts of the other patients discussed during the hearing. GX 15 at 49 (section marked HPI).

57. Dr. Kennedy testified that he also found evidence of abnormal drug screens, even on M.H.'s initial visit. Tr. 313–14; GX 15 at 63. On some occasions, M.H. tested positive for illicit substances. *See* GX 15 at 56 (positive for THC, cocaine, PCP); GX 15 at 53 (positive for amphetamines); Tr. 314–15. In other cases, he tested negative for drugs that had been prescribed. GX 15 at 51 (positive for opiates and oxycodone when patient also prescribed alprazolam and carisoprodol); GX 15 at 49 (same); GX 15 at 47 (same); GX 15 at 40 (UDS negative for all drugs while patient was prescribed oxycodone oxymorphone, alprazolam, and carisoprodol); GX 15 at 39 (UDS negative for all drugs); GX 15 at 36 (UDS positive only for oxycodone). In these cases, Dr. Kennedy testified, there was no evidence that Respondent addressed the abnormalities other than to order repeat tests. Tr. 313–20.

58. Dr. Kennedy also reviewed the prescriptions for M.H. identified as GX 19. These included alprazolam, oxymorphone, carisoprodol, and oxycodone. Tr. 325–27.

59. Dr. Kennedy testified that, in his view, Respondent prescribed controlled substances to M.H. despite evidence that M.H. may have been addicted to the habit of using controlled substances. Tr. 327. He testified that Respondent made no effort to cure M.H.'s habit. *Id.* Dr. Kennedy further testified that Respondent: (1) Failed to perform an adequate assessment in consideration of the patient's pain, physical and psychological function; (2) failed to evaluate the patient's history and potential for substance abuse; (3) failed to determine a recognized medication indication for the use of controlled substances; (4) failed to create a written treatment plan tailored for the individual needs of the patient; (5) failed to consider the need for further testing, consultation, referrals, or use of other treatment modalities; (6) failed to discuss the risks and benefits of the use of controlled substances; (7) failed to do a documented periodic review of the patient's care at reasonable intervals in view of the individual circumstances of each patient; and (8) failed to keep complete and accurate records of the care provided to M.H. Tr. 327–29.

60. Dr. Kennedy testified that the controlled substances issued to M.H. were not issued in the usual course of professional practice. Tr. 329.

Patient M.P.

61. Dr. Kennedy testified that M.P. was being treated for low back, neck, hip, and shoulder pain. Tr. 331. Dr. Kennedy testified that the physical exam used to justify prescribing controlled substances for M.P. was inadequate. Tr. 334. As he explained, M.P. was diagnosed with degenerative disc disease and right shoulder pain. To determine whether M.P. had shoulder pain, Dr. Kennedy testified, a physician would have to test the patient's ''range of motion as far as extension, flexion, abduction . . . tenderness to palpation specific to the shoulder.'' Tr. 335. With respect to degenerative disc disease, Dr. Kennedy testified that Respondent should have found, for example, that the ''dorsal lumber and C-spine range of motion'' was ''decreased in all directions.'' *Id.* Dr. Kennedy testified he saw no such findings in Respondent's medical record. Tr. 334–35. Dr. Kennedy also testified that M.P.'s pain level was inconsistent with other information in the record.

62. Dr. Kennedy also testified that, throughout M.P.'s medical records, Respondent expressed a need to obtain M.P.'s prior medical records, but Respondent never followed through. GX 7 at 1, 59, 68; Tr. 337–38. This included obtaining M.P.'s x-rays, MRI report, and the dismissal form from her prior physician. *Id.*

63. Dr. Kennedy testified that M.P. manifested signs of abuse/diversion which were not adequately addressed. Initially, M.P. tested positive for buprenorphine, benzodiazepines, oxycodone, and THC. GX 7 at 68. According to the pharmacy report, which was part M.P.'s medical chart, buprenorphine had never been prescribed. Tr. 338–39; GX 7 at 19. Dr. Kennedy also discussed that there was mention of ''termination paperwork from a previous physician,'' another red flag for abuse and/or diversion. Tr. 342. Dr. Kennedy pointed out ''highly conflicting'' information in M.P.'s medical chart. Tr. 345. For instance, M.P. listed her occupational disability as both ''9'' and ''10,'' but stated she works ''45–60 hours weekly'' as a waitress. GX 7 at 9–10. Dr. Kennedy also questioned M.P.'s truthfulness when she denied that she had ever been in a drug treatment program (GX 7, 13). However, following a heroin overdose, she told Respondent that she refused to go into such a program because she had tried drug treatment *before.* GX 7 at 57 (section marked ''HPI''). Dr. Kennedy also pointed out several abnormal drug screen results. In GX 7, page 58, there is a reference to a positive test for THC, opioids, and benzodiazepines, none of which had been prescribed. Tr. 347.

64. M.P. overdosed on heroin in Respondent's waiting room. GX 7 at 25; Tr. 340–41. However, according to Dr. Kennedy, Respondent incorrectly treated M.P. with Suboxone (buprenorphine).

65. Dr. Kennedy testified that Respondent repeatedly issued prescriptions for controlled substances to M.P. despite the fact she was addicted to the habit of using controlled substances. Tr. 348. Also, up until the point M.P. overdosed on heroin, Respondent made no effort to cure M.P.'s habit. Tr. 348–49. Dr. Kennedy also testified that, with respect to M.P., Respondent: (1) Failed to perform a sufficient physical examination; (2) failed to perform an adequate assessment in consideration of the patient pain, physical and psychological function; (3) failed to record an adequate history of potential substance abuse; (4) failed to determine a recognized medical indication for the use of controlled substances; (5) failed to create a written treatment plan tailored for the individual needs of the patient; (6) failed to take a pertinent medical history and perform a physical examination as well as perform further testing, consultation, referrals. And the use of other treatment modalities; (7) failed to discuss the risk and benefits of the use of controlled substances; (8) failed to do a documented periodic review of M.P.'s care at reasonable intervals in view of the individual circumstances; and (9) failed to keep

complete an accurate medical records of the care provided to M.P. Tr. 348–50.

66. Dr. Kennedy also testified that the prescriptions issued to M.P., including those in GX 21, were issued outside the usual course of professional practice, and that Respondent lacked a medical justification for issuing the prescriptions. Tr. 352.

67. With respect to patients, B.C, C.F., M.H., M.W., and M.P., Dr. Kennedy testified that the prescribing of controlled substances to these patients was dangerous. Tr. 352. As a basis for that opinion, he cited: (1) Abnormal drug screens that were ''essentially ignored,'' (2) the lack of documentation about the patients' status; (3) medical records that were not credible; (4) and maintaining patients on scheduled medications, sometimes at high dosages ''without having honest, accurate, complete medical records.'' Tr. 352–53. He testified that ''[b]ecause medical records will instruct other people who look'' at the patients later, a medical record that ''simply doesn't make sense or [has] something that is in conflict,'' can ''present a dangerous situation.'' Tr. 353.

Respondent's Falsification

68. DI testified that Respondent submitted an application to renew his DEA COR (No. BO4959889) on November 6, 2019. Tr. 529; GX 26. She testified that Respondent answered ''no'' to the third liability question on the application. Specifically, the question sought to determine whether Respondent had ever ''surrendered for cause or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation.'' Tr. 530.

69. DI introduced a document outlining an administrative action against Respondent, titled ''Notice of Charges and Memorandum for Assessment of Civil Penalties,'' submitted May 1, 2019, by the Tennessee Department of Health. GX 29; Tr. 531. As the document states, Respondent was charged with, among other things, prescribing ''narcotics and other medications and controlled substances in amounts and/or duration that were not medically necessary, advisable, or justified for a diagnosed condition.'' GX 29 at 5.

70. DI introduced a document from the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part III (''Chancery Court''), staying the proceedings brought by the Tennessee Department of Health, [omitted] and imposing restrictions on Respondent's license as conditions of the stay. Those restrictions included prohibiting Respondent from: (1) Writing prescriptions; (2) supervising or collaborating with any mid-level practitioners for the writing of prescriptions; and (3) providing direct patient care including but not limited to diagnosing, treating, operating on or prescribing for any person. GX 27 at 2–3; Tr. 533–34. The order is dated May 17, 2019, approximately three months before Respondent submitted his renewal application. GX 27 at 4.

71. DI introduced a document, titled Agreed Order, dated August 21, 2018. GX 28. DI testified that the Order provided that Respondent must surrender his Tennessee Pain Management Clinic Certificate (''Pain Clinic Certificate''), No. 246, as a result of violations related to the prescribing of controlled substances. *Id.* at 5–7.

72. DI testified, as a result of having surrendered his Pain Clinic Certificate and the restrictions placed upon his medical license by the Chancery Court, that Respondent did not answer truthfully on his renewal application. Tr. 536.

Analysis

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked, and any applications should be denied, because the Respondent [has committed such acts as would render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4); 21 U.S.C. 823(f) and in particular the Government relies on Public Interest Factors Two (the Respondent's experience conducting regulated activity) and Four (the Respondent's compliance with state and federal laws related to controlled substances)]. ALJ Ex. 1.[29] In the adjudication of a revocation of a DEA COR, the DEA bears the burden of proving that the requirements for such revocation are satisfied. 21 CFR 1301.44(e). Where the Government has sustained its burden and established that a respondent has committed acts that render his registration inconsistent with the public interest, to rebut the Government's *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,734 (2009).

Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

The Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie* v. *DEA,* 419 F.3d 477, 482–83 (6th Cir. 2005); *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.,* 74 FR 17,529, 17,543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was ''probably at fault'' for some misconduct); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (noting, on remand, that despite the respondent's having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Medicine Shoppe–Jonesborough,* 73 FR 364 at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).*[R]

Tennessee Law

As a licensed medical doctor in Tennessee, the Respondent was subject to TENN. CODE ANN. § 63–6–214(b)(12) through (14),[30] as those provisions

[29] In its GPHB, the Government argues Factors Two and Four should be combined for a joint analysis.

*[R] Remaining text omitted for brevity and clarity.

[30] T. C. A. § 63–6–214. License denial, suspension, or revocation; grounds; examination; investigations; abstract of record; report; standard of care; disclosure of records; screening panels; hearings; orders

(a) The board has the power to: (1) Deny an application for a license to any applicant who applies for the same through reciprocity or otherwise; (2) Permanently or temporarily withhold issuance of a license; (3) Suspend, or limit or restrict a previously issued license for such time and in such manner as the board may determine; (4) Reprimand or take such action in relation to

Continued

pertain to ''dispensing, prescribing, or otherwise distributing'' controlled substances. Specifically, section 63–6–2 l 4(b)(12) prohibits a physician from prescribing controlled substances ''not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition.'' Additionally, section 63–6–214(b)(13) prohibits a physician from prescribing controlled substances to a person ''addicted to the habit of using controlled substances'' without ''making a bona fide effort to cure the [patient's] habit.'' To determine a violation of these provisions, the Tennessee Board of Medical Examiners uses a nonexhaustive list of guidelines (''the guidelines'') found in TENN. COMP. R. & REGS. 0880–02-.14(6)(e).[31] The guidelines require that a physician: (1) Take a documented medical history; (2) conduct a physical examination; and (3) perform an adequate ''assessment and consideration of the [patient's] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.'' TENN. COMP. R. & REGS. 0880–02–.14(6)(e)(3)(i). Additionally, Rule 0880–02–.14 (6)(e) requires physicians to create a ''written treatment plan tailored for the individual needs of the patient'' that considers the patient's ''pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.'' It also requires the physician to ''discuss the risks and benefits of the use of controlled substances,'' complete a ''documented periodic review of the care . . . at reasonable intervals,'' and ''keep [c]omplete and accurate records of the care.'' *Id.* at 0880–02–.14(6)(e)(3)(ii)–(v).

Exclusion of the Respondent's Testimony

The Government objected to the Respondent's testimony *S because prior to the hearing Respondent identified that he may testify regarding the material falsification allegation, but said he would not testify regarding the prescribing allegations as he has another matter pending. However, at the hearing, the Respondent sought to present testimony regarding the allegations surrounding his prescribing. He did not offer testimony regarding the material falsification allegation. [The ALJ permitted all portions of the Respondent's testimony that could have been reasonably anticipated by the Government and I have considered Respondent's testimony in reaching my decision. I find it unnecessary to reach any further conclusions and have omitted the remainder of the ALJ's analysis for brevity, as the Government did not take exception to the ALJ's ultimate decision.] [32] [33]

Accurate and Complete Medical Records

The Government alleges that the Respondent failed to maintain accurate and complete medical records for each of the subject patients, as mandated by the relevant Tennessee regulations and standard of care. The medical records contain the results of physical examinations and other tests, which did not occur on the reported dates. The records are rife, across all of the subject patients, with identical findings, suggesting the subject examinations either did not take place, or the results were not reported accurately.

In explaining the identical anxiety and insomnia indications written in each of his patients' charts to justify benzodiazepines, the Respondent testified that his patients exhibited the same symptoms which is common among anxiety patients. However, the fact that UC's chart reflected that he had the same anxiety indications and other indications identical to the other five patients, despite the fact that he testified credibly that he did not complain of any anxiety symptoms, greatly reduces the credibility of the Respondent's subject explanations. Tr. 79–80. Indeed, most of the indications within UC's chart were unreported by him.[34] UC reviewed Government Exhibit 5 and noted that he was not asked about any of the reported symptoms. Tr. 81. As to why individual patients had the same indications within the chart for long periods of time, the Respondent maintains that the subject record findings were carried forward from prior tests, as permitted by the Tennessee standard of care. [However, Dr. Kennedy testified, ''there is no regulation anywhere that allows a physician [to] document physical exam findings that he did not perform. That's not acceptable under any regulations.'' Tr. 652.]

Similarly, the Respondent justified reporting test results when no tests occurred, as he claimed was permitted by the Tennessee standard. Prior test results were simply carried forward within the electronic medical record. I credit Dr. Kennedy's opinion that reporting test results purported to have occurred on a particular date, which did not then occur, is contrary to the Tennessee standard of care. Even a casual review of the relevant Tennessee regulations reveals the prominence of the Tennessee physician's obligation to accurately document. He is required to establish a ''written treatment plan tailored for the individual needs of the patient'' that considers the patient's ''pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.'' It also requires the physician to perform a ''documented periodic review of the care . . . at reasonable intervals,'' and ''keep [c]omplete and accurate records of the care.'' *Id.* at 0880–02–.14(6)(e)(3)(ii)–(v).

Common sense itself would refute the Respondent's position. Indications and exam results carried forward, perhaps for months or even years, defeats the whole purpose of medical records, which is to inform the practitioner and other potential treating practitioners of the patient's true and present condition, progression of disease or efficacy of treatment. [Dr. Kennedy testified that

disciplining an applicant or licensee, including, but not limited to, informal settlements, private censures and warnings, as the board in its discretion may deem proper; or (5) Permanently revoke a license.

(b) The grounds upon which the board shall exercise such power include, but are not limited to: . . . (12) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition; (13) Dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient; (14) Dispensing, prescribing or otherwise distributing any controlled substance, controlled substance analogue or other drug to any person in violation of any law of the state or of the United States; . . . (emphasis added).

[31] Tenn. Comp. R. & Regs. 0880–02–.14 SPECIALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE. [Omitted text of guidelines for brevity.]

*S Text omitted for brevity.

[32] [Omitted original text in which footnote appeared.]

[33] [Omitted original text in which footnote appeared.]

[34] UC noted that despite his records stating that ''[UC] . . . has had a history of insomnia and anxiety for several years,'' he did not report anxiety symptoms of shortness of breath, of having palpitations, sweating, dizziness, or shaking. Tr. 79–80; GX 5. The medical record also reflects that he had a headache that day, despite the fact that UC did not report having a headache, dizziness, nausea, or vomiting. Tr. 80; GX 5. No one questioned UC as to whether he had abdominal pain, diarrhea, and constipation. Tr. 80–81.

here the documentation did not ''make sense'' and was ''in conflict,'' which ''present[s] a dangerous situation'' for ''other people who look at [the records].'' Tr. 353. Based on this testimony, one could conclude that wrong records are worse than no records at all, as they would mislead other treating practitioners. And as Dr. Kennedy testified, here ''you have a medical record which shows consistently documentation . . . that did not occur, that is outside the scope of acceptable medical practice, and it does not support legitimate prescribing of scheduled agents.'' Tr. 652.]

The Respondent has conceded there are factual errors in the subject records. Although UC's chart contains an entry that his pharmacy printout was reviewed, the Respondent conceded that no pharmacy printout was reviewed and that such entry was in ''error.'' Tr. 631–32; GX 5 at 6. M.H.'s chart contains the inconsistent finding of long-term insomnia, but with an entry of sleeping well. Tr. 640–41; GX 15 at 47–48. The Respondent conceded they were inconsistent entries. Tr. 641. Additionally, while M.W.'s chart reflects he had been dismissed, M.W. continued to be seen for months afterwards, without any further explanation documented in the record. Tr. 259–60. And, Respondent reported a ''history of insomnia for several years'' for M.H.; however, this note first appears 19 months into treatment. GX 15; Tr. 49.

Additionally, there are conflicts between the Respondent's written notes and the electronic medical records. Documents UC filled out are missing from his chart that was seized from the Respondent. The electronic medical record for a visit by M.W. does not contain the handwritten information recorded in GX 10 at 8. Tr. 250–51; GX 10 at 9. Instead, the results of the physical exam mirror those findings made for UC, rendering M.W.'s chart not credible. Tr. 251–52. The physical exam notes written for C.F. revealed essentially normal findings, however the electronic records for this visit failed to include these findings. Tr. 271; GX 11 at 69. Instead, under physical exam, the same language that is duplicated so often in the records, appears. Tr. 272. Dr. Kennedy noted the hand-written exam notes for M.H. did not appear in the electronic medical records. Tr. 325–36; GX 7 at 68. Instead the same physical exam notes duplicated throughout the records appear. Tr. 336, 351. So, at times, verbatim records were repeatedly and inaccurately inputted into the electronic medical records when actual, accurate indications were available.

Dr. Kennedy noted the actual pain level was left blank at nine consecutive encounters with B.C., suggesting it was being added later and that the record was being fabricated. Tr. 294–95; GX 13 at 159; GX 14 at 8.

For these reasons and those discussed below, I find the Government has sustained its burden in proving the Respondent failed to maintain accurate and complete medical records as to the subject patients, in violation of TENN. COMP. R. & REGS. Rule 0880–02–.14 (6)(e).*T [I further find that each of the relevant prescriptions at issue in this matter were issued outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records.]

Undercover

The Government alleges the Respondent failed to perform an adequate physical exam; take an adequate medical history; assess UC's pain, physical and psychological function; assess the patient's history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of oxycodone; and failed to create a legitimate written treatment plan for UC's individual needs or to discuss the risks and benefits of the use of oxycodone with UC. At three level one visits, the chart falsely reflects the results of physical exams, which did not occur. The Government alleges the Respondent's continued prescribing of controlled substances to UC was without a legitimate medical purpose and/or outside the usual course of professional practice.

Dr. Kennedy reviewed the chart and the undercover videos for UC, the undercover agent. Tr. 216–17, 363; GX 6. Dr. Kennedy acknowledged that in scheduling the first visit, the Respondent's staff instructed UC to bring certain medical records to his first visit, the previous three physician notes, his discharge summary, the record of the previous three months prescriptions and an MRI, an appropriate protocol in Dr. Kennedy's opinion. Tr. 364–65; GX 3 at 1.

The Respondent testified that he took a medical history, a condition-specific physical exam for low back pain, and reviewed the MRI (GX 6) of UC. Tr. 575–80.[35] The Respondent agreed that he spent no more than fifteen minutes with UC in the examination room. Tr. 621. The Respondent maintains that he performed the required assessments related to pain, physical and psychological function, and history and potential for drug abuse. Tr. 582. This involved reviewing the paperwork UC filled out, authenticating that paperwork, the triage of UC by staff, UDS, and a final review of the paperwork by the Respondent with the patient. Tr. 583, 584. UC recalled the Respondent going over his paperwork with him, but could not remember the extent of the review. According to UC, the triage by other staff was minimal, sporadic or non-existent. Tr. 59. UC cited Dr. Morgan, who did not exist, in his medical history paperwork, yet the staff did not discover that fact. None of UC's paperwork could be authenticated, as designed. UC's history was similarly designed to be a ''dead end.'' Tr. 238. [Accordingly, I find Respondent's testimony that he authenticated UC's paperwork to lack credibility.] There was no review of UC's psychological functioning, although he was diagnosed with anxiety.[36] The Respondent's instant claims are belied by the record.

The Respondent explained that a patient's pain is very subjective. After reviewing his paperwork, including the MRI, examining UC and speaking with him, the Respondent claimed that he had no reason not to treat him as someone who has genuine pain. Tr. 588. UC's statement that he had used controlled substances for his pain and that ibuprofen was not working supported the conclusion that his pain was long standing, and warranted a Schedule II medication. [Omitted for relevance.]

Dr. Kennedy opined that UC's medical chart did not justify the prescribing of controlled substances.[37] Tr. 230–31, 240; GX 18 at 1, 3. Although there was an actual MRI report of UC, Dr. Kennedy found the MRI report internally inconsistent [which Dr. Kennedy testified should have caused Respondent to question the MRI.] Tr. 387–94. Dr. Kennedy opined that it

*T Omitted for brevity.

[35] The Respondent noted that his physical exam of C.R. was not captured by the video of the encounter. The camera was pointed at the wall. Tr. 581–82.

[36] Where practitioner asked his patient whether there was ''any other medication he took for anxiety,'' and where the practitioner made no effort to determine the extent of the patient's symptoms before prescribing Xanax to him, the practitioner was not engaged in the legitimate practice of medicine but instead was dealing drugs. *Henri Wetselaar, M.D.,* 77 FR 57,126, 57,132 (2012).

[37] The Respondent cautioned that in reviewing his electronic medical record, it often referred to other records. For example, under history of present illness (HPI), he would often reference the initial encounter paperwork, as included by reference, in the electronic record. Tr. 592.

would be outside the usual course of professional practice to prescribe controlled substances based on this MRI alone.*U Tr. 483–86.[38] UC was being treated for complaints of back pain. However, Dr. Kennedy opined that the physical exam detailed in the chart was not sufficient under Tennessee standards, and the exam that was performed revealed, essentially, a normal back. Tr. 217, 231, 237, 396–97, 440. On rebuttal, Dr. Kennedy reiterated this assessment after listening to the Respondent's explanation. Tr. 651–52.

The Respondent explained his treatment of UC. After the UC filled out extensive paperwork, the initial examination by the Respondent consisted of observing UC, touching his back and causing the patient to lift his leg. Tr. 217–18, 359–60; GX 6 at 6. Dr. Kennedy noted the taking of vital signs and a general exam within the chart; however, he observed that from viewing and listening to the video of this visit, such exam was not performed as described, or not performed at all. Tr. 218–19, 379–81; GX 6, 4.[39] The prior medical history reported by UC was facially suspicious and constituted a red flag. Tr. 238. UC reportedly came from a clinic, which had been shut down, and provided medical records from a Nurse Practitioner whose license had been suspended. Tr. 238. The Respondent conceded UC was a challenge, as the clinic he reported had been closed, and he could not obtain the pharmacy information, so the Respondent could not verify that source. Tr. 583–85. As UC's prior medical records could not be confirmed, the Respondent claimed that he prescribed a dosage appropriate to a patient just starting opioid treatment. Tr. 589–90.

The Respondent expected his patients to be honest and truthful with him consistent with the DEA Physician's Manual, which requires patients to be honest with their doctors. Tr. 586–87.[40] In his Post-hearing Brief, the Respondent continues to complain of the use of an undercover agent, who operated under ''false colors'' to ensnare the Respondent, and his disappointment that the Tribunal does not share his sentiment. The fact of the matter is, there is nothing illegal or improper regarding the Government's use of undercover agents.[41] Even if I shared the Respondent's sentiment, and opined that the use of undercover agents was somehow unfair, this is not a court of equity.[42] We operate strictly by statute and regulation [and here the evidence clearly establishes that Respondent's prescribing to UC was outside the usual course of professional practice and beneath the standard of care in violation of the CSA and its implementing regulations.]

Dr. Kennedy opined that UC's obfuscation, false and misleading statements to the Respondent and staff, did not relieve the Respondent's obligation to investigate any suspicious circumstances. Tr. 375–78, 382. The Respondent misperceives his role. [Omitted for relevance.] Physicians must be wary of patients seeking controlled substances for abuse and diversion. Although the Respondent's staff was suspicious of UC's prior records, as they appeared to have been altered, their concern appeared to be that the UC was perhaps law enforcement, ''try[ing] to bring the Respondent down,'' rather than someone attempting to divert or abuse controlled substances. UC presented as a patient with no verified history, his paperwork contained indications of alteration, he complained of pain without overt indications; yet, the Respondent opined that the record supported his conclusion that UC was legitimately in pain. Dr. Kennedy disagreed and opined that it is the practitioner's responsibility to investigate suspicious circumstances and to resolve them prior to prescribing controlled substances.

Dr. Kennedy noted that the physical exam included in this first visit by UC was repeated verbatim in most of the approximately twenty charts he reviewed. Tr. 220; GX 7 at 65 (M.B.), GX 9 at 69 (M.W.). The Respondent explained that he performed a physical exam at the initial visit of each of his patients, as required by the Tennessee pain management guidelines. Tr. 594. Physical exams thereafter are at the discretion of the physician. Tr. 594. Although UC had five visits to the clinic, only two involved encounters with the Respondent. The other three visits were ''level one'' visits, in which UC met with the Respondent's staff only. Tr. 622–28, 645–50. Although the medical records reflect a physical examination took place at the level one visits, there was no physical exam. Instead, the Respondent explained he and his staff had carried forward results from prior examinations to later visit records with new findings added, which Dr. Kennedy opined was not permissible. Tr. 623–28; *supra* ''The Analysis, Accurate and Complete Medical Records.''

Dr. Kennedy noted UC's chart identified him with a ''long-standing history of insomnia and anxiety,'' however the chart contained no examination that would support such findings. Tr. 233–34; GX 5 at 4. Additionally, the reported symptoms of the anxiety finding, ''palpitations, sweating, dizziness, shaking'' was repeated almost universally throughout the medical records reviewed as to patients diagnosed with insomnia and anxiety. Tr. 233–34. Similarly, the visit of October 17, 2017, by UC contains extensive medical findings, but the video of that visit does not support those findings. Tr. 235–37; GX 5 at 5. The video does reveal the Respondent asking UC, ''how is your sleep'' to which UC responds, ''not good.'' Tr. 236. The Respondent then prescribes Elavil, or amitriptyline [which is not a controlled substance and is not at issue in this case.] Tr. 236. Dr. Kennedy made a similar observation as to extensive medical findings on subsequent visits in which UC was not seen by the Respondent. Tr. 235–37; GX 5 at 3–5. Although the medical records state that a physical examination took place at the level one visits when no physical examination occurred, the Respondent explained that it was permissible in medical record-keeping to carry forward results from prior examinations to later visit records, with new findings added. Tr. 623–28. Dr. Kennedy disagreed, noting that it is never permissible for charts to reflect examination results, when no exam occurred. Tr. 652–53. At UC's second visit, he was called back to the triage room where the nurse asked him his weight to which he replied, ''210,'' and if his blood pressure was ok to which he responded, ''yes.'' Tr. 59. He was not weighed, nor was his blood pressure taken. Dr. Kennedy did not believe UC's chart reflected the Respondent maintained a truthful and accurate record of the treatment. Tr. 232; GX 3; 4. I credit Dr. Kennedy's

*U This sentence has been modified for clarity.

[38] The Agency has previously found based on credible expert testimony that relying exclusively on MRI results for prescribing controlled substances is unprofessional conduct in the applicable state. *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,140 (2012).

[39] The Agency has previously found that falsifying a patient's medical record to indicate that respondent performed a physical exam but where video/audio recordings show that a physical was never conducted demonstrate that respondent knowingly violated the CSA. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Bernard Wilberforce Shelton, M.D.,* 83 FR 14,028, 14,042 (2018).

[40] ''A practitioner who ignores the warning signs that her patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if she is merely gullible or naïve.'' *Krishna-Iyer, M.D.,* 74 FR 460 n.3.

[41] [Omitted for relevance.]

[42] Administrative Law Judges of the DEA ''lack the authority to exercise equitable powers'' in determining whether a registration is consistent with the public interest. *The Main Pharmacy,* 80 FR 29,022, 29,024 (2015).

opinion regarding the results of non-existent tests.

On the basis of the deficient physical exam, Dr. Kennedy opined that prescribing controlled substances to UC was not justified. Although the Respondent prescribed a much lower MME than UC had purportedly been on before, it was not consistent with the Tennessee standard, which would require observation, looking for spasms, lumbar range of motion maneuvers, straight leg raise test, neurologic exam and motor deficits. Tr. 221–25, 239, 382–83; GX 5 at 6. Other deficiencies in the records that caused the controlled substance prescriptions for UC to be unjustified included the deficiency in the prior medical records provided by UC. Tr. 228. On a positive note, UC's chart revealed an exploration of alternate treatment by prescribing Meloxicam, and offering injections. Tr. 228–29.

The Respondent testified he prepared an adequate written treatment plan with appropriate treatment goals and therapy. Tr. 590–91. However, Dr. Kennedy opined UC's chart did not include an adequate treatment plan. Tr. 229. The records reveal a deficient discussion regarding the risks and benefits of controlled substance medication. Tr. 231. Dr. Kennedy deemed the diagnosis of degenerative disc disease unjustified on the basis of the chart and MRI. Tr. 240–42; GX 5 at 2, 6; GX 6 at 12. I find Dr. Kennedy's assessments credible.*[V]

[In accordance with Dr. Kennedy's credible and unrebutted expert testimony, and for the reasons above, I find that the three oxycodone prescriptions Respondent issued to UC were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of UC's pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for UC's individual needs or to discuss the risks and benefits of the use of oxycodone with UC. Additionally, and in accordance with Dr. Kennedy's testimony, I find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for UC.]

Allegations Common to the Five Remaining Patients

With respect to the Respondent's treatment of M.H., C.F., M.P., B.C., and M.W. (''the five patients''), the Government alleges the prescriptions for controlled substances were not issued in the course of professional practice inasmuch as the Respondent failed to: (1) Take an adequate medical history; (2) perform a sufficient physical examination; and (3) perform an adequate ''assessment and consideration of the (patients'] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.'' The Respondent also failed to create a ''written treatment plan tailored for the individual needs'' of each of the five patients that considered each of the patient's ''pertinent medical history and physical examination, as well as, the need for further testing, consultation, referrals, or use of other treatment modalities.'' The Respondent also failed to: (1) ''discuss the risks and benefits of the use of controlled substances'' with patients M.H., C.F., M.P., B.C., and M.W.; (2) conduct a ''documented periodic review of the[ir] care . . . at reasonable intervals in view of the individual circumstances'' of each patient; and (3) keep ''(c]omplete and accurate records of the care provided.'' As such, the Respondent's conduct violated TENN. CODE ANN. § 63–6–214(b)(12) and TENN. COMP. R. & REGS. 0880–02 .14(6)(e)(3)(i)–(v).

The Government further alleges the prescriptions the Respondent issued to M.H., C.F., M.P., B.C., and M.W. failed to comply with Tennessee state law in that they did not conform to accepted and prevailing medical standards in Tennessee, and thus, were issued outside the usual course of professional practice. The Respondent's conduct, viewed as a whole, ''completely betrayed any semblance of legitimate medical treatment.'' *Jack A. Danton, D.O.,* 76 FR 60,900, 60,904 (2011).

By issuing these prescriptions for controlled substances, the Respondent failed to take reasonable steps to guard against diversion of controlled substances. *See David A. Ruben, M.D.,* 78 FR at 38,382; *Beinvenido Tan, M.D.,* 76 FR 17,673, 17,689 (2011); *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,974 (2010); *Physicians Pharmacy, L.L.C.,* 77 FR 47,096 (2012).

Allegations as to Specific Patients

As to the allegations regarding each of the subject patients, in his Posthearing Brief (PHB), the Respondent argues the Government's case suffers weakness by the Government's failure to present the relevant patients' testimony, testimony of relevant pharmacists, any evaluation regarding the volume of the Respondent's prescriptions in relation to other physicians, the absence of any complaints to law enforcement, and no physician testimony that the subject patients were seeking detox due to the Respondent's excessive prescribing.*[W]

In the context of the allegations and evidence, none of the above constitutes necessary evidence to prove the allegations. Indeed, I struggle to see any relevance to such evidence in the context of the allegations made.

Patient M.W.

The Government alleged that the Respondent regularly and improperly issued prescriptions for large quantities and dosages of oxycodone, oxymorphone, alprazolam, and carispoprodol to Patient M.W. The Government further alleged that the initial physical examination and medical history did not justify the continued prescribing of controlled substances and the subsequent physical examinations did not meaningfully evidence any chronic pain condition. The Government alleged that the Respondent failed to: (1) Order and obtain diagnostic studies; and (2) adequately address numerous instances in which the patient had inconsistent drug screens indicating possible diversion, abuse, and/or use of illegal controlled substances. The Government further alleged that much of the medical record for M.W. was fabricated and appeared to be copied from records of other patients, whose records contained identically worded assessments. Finally, the Government alleged the Respondent documented that the patient provided ''informed consent'' when no informed consent document could be located. Additionally, the Government alleged the Respondent failed to address substantial evidence that M.W. was engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. 63–6–214(b)(13).

In support, the Government offered the testimony of its expert, Dr. Kennedy.

*[V] Omitted. The ALJ found that the diagnosis of C.R. with insomnia was appropriate. The issue relevant to this case is whether or not there was a recognized medical indication for the use of oxycodone. The medication prescribed as a result of the insomnia diagnosis was not a controlled substance and was not directly at issue in this case. Accordingly, it is not necessary to determine whether the records contained sufficient evidence to support the insomnia diagnosis, because it is not relevant to the case.

*[W] It is also noted that Respondent did not offer any of this testimony in an attempt to rebut the Government's case.

Dr. Kennedy identified his ''chart review'' for M.W. Tr. 243–44; GX 9, 10. M.W. was diagnosed with low back pain, yet Dr. Kennedy credibly opined that the records did not support such diagnosis. Tr. 245–46; GX 9 at 14; GX 10 at 3. The notes did reference back to M.W.'s initial encounter. Tr. 441. The Respondent testified M.W. was first seen in January 2013. Tr. 595. M.W. was a gunshot victim to whom the Respondent prescribed alprazolam. This, according to Respondent, was based on the history and physical exam. Tr. 593, 635–36; GX 9 at 69. The Respondent claimed he obtained a medical history, conducted a physical exam, performed an adequate pain, physical, and psychological assessment, history and potential for substance abuse. Tr. 596. The Respondent claimed that he prepared a written treatment plan. Tr. 601.

Yet, Dr. Kennedy countered there were no findings in the record that would support a chronic pain condition and justify prescribing controlled substances. Tr. 246–47. Dr. Kennedy found no credible physical exam to justify the diagnosis. Tr. 247, 265. Dr. Kennedy testified that the Respondent did not assess M.W.'s pain level, physical and psychological functioning, history, potential for drug abuse, or coexisting diseases. Tr. 265. The Respondent did not follow a legitimate written treatment plan. The physical exam findings were generally normal findings, except for limited range of motion at the lumbar spine. Tr. 247; GX 10 at 7. M.W. reported a pain level, at worst, at 10 of 10, and at best, 6 of 10. Tr. 248–49; GX 9 at 19; GX 10 at 8. M.W.'s reported pain level was inconsistent with the generally normal results of the physical exam. Tr. 249–50. The electronic medical record for this visit does not contain the handwritten information recorded in GX 10. Tr. 250–51; GX 10 at 9. Instead the results of the physical exam mirror those findings made for UC, rendering M.W.'s chart not credible. Tr. 251–52. This finding was bolstered by ''wildly'' inconsistent UDS results. Tr. 252–55; GX 9 at 2–4, 9–11, 84, 96, 102. After a series of inconsistent UDS, the Respondent noted in M.W.'s chart that M.W. was dismissed from pain management with one-month notice. Tr. 258; GX 9 at 84. Yet, at the same visit in which he had been notified he will be dismissed, the history of present illness reports the patient is compliant and consistent. Tr. 258. Dr. Kennedy deemed the chart not credible, accordingly. Tr. 259. However, despite being dismissed, M.W. continued to be seen for months afterwards without any further explanation in the medical records. Tr. 259–60.

The Respondent explained that the evaluation of the patient's potential for drug abuse is an ongoing evaluation with UDS, involving office screens, confirmatory lab screens, and pill counts. Tr. 596–98, 600. Respondent testified that once a lab-confirmed inconsistent UDS is discovered, the Respondent initiates a dismissal process. Tr. 598–600. The Tennessee pain management guidelines leave it to the physician's discretion on the handling of confirmed inconsistent UDS results. Tr. 598–99.[43] The Respondent gives the patient a month to come into compliance. Tr. 600. If he has a consistent UDS within the month, the patient is permitted to remain in treatment. Tr. 601. The Respondent claimed was able to bring M.W. back into compliance through counseling, however, the chart only documents that the patient was counseled as to the inconsistent UDS without identifying any specific information. Tr. 637–38. Dr. Kennedy later conceded that M.W. was reinstated consistent with the Respondent's described office protocol. Tr. 459–60. The Respondent continued to prescribe him alprazalam, amitriptyline, oxycodone, oxymorphone and Soma. As noted earlier, Respondent's documentation of these events and his handling of M.W.'s inconsistent UDS was clearly outside the Tennessee standards.

Regarding the alprazolam prescriptions, Dr. Kennedy found it unjustified based on the information supporting the anxiety diagnosis. Tr. 260–61, 442–44; GX 9 at 85. Dr. Kennedy noted the indications for anxiety were not supported by the findings within the chart, and mirrored those in the charts for UC and other patients. Tr. 261–62. In his PHB, the Respondent argued that Dr. Kennedy conceded a gunshot victim would have PTSD; however, I credit Dr. Kennedy's opinion that the chart did not justify the alprazolam prescription.

Although Dr. Kennedy opined M.W. should have been physically examined periodically during his treatment, the charts suggest he was not examined again following his first examination. Tr. 262. Dr. Kennedy further opined that as M.W. was a 25-year-old diagnosed with degenerative disc disease, the Tennessee standards would require diagnostic testing, such as an MRI to confirm the diagnosis. Tr. 262, 447–48. Dr. Kennedy found M.W.'s chart ''not credible and fabricated.'' Tr. 263–64, 266; GX 10 at 5, 23. He noted that of 93 of 98 total visits shared the identical findings for the physical exams and ROS. Tr. 264. Similarly, Dr. Kennedy found the diagnosis of insomnia not credible. Tr. 264. A finding of drug abuse and chemical dependency would have been supportable, but such indications were not sufficiently addressed by the Respondent. Tr. 264–65. The credible findings within M.W.'s chart did not support the prescribing of controlled substances, and the subject prescriptions were issued outside the usual course of professional practice. Tr. 267–68. I credit Dr. Kennedy's opinions in finding the Respondent's subject actions fell below the Tennessee standards, and the controlled substances were prescribed outside the Tennessee standards.

[In accordance with Dr. Kennedy's credible and unrebutted expert testimony, and for the reasons above, I find that the twenty-six identified prescriptions for alprazolam, carisoprodol, oxycodone, and oxymorphone that Respondent issued to M.W. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of M.W.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for M.W.'s individual needs. Tr. 265. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for M.W. Tr. 265–66. Finally, in accordance with Dr. Kennedy's testimony, I find that M.W. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent. Tr. 264–64.]

Patient C.F.

The Government alleged that from August 2014 through August 2018, the Respondent regularly issued prescriptions for oxycodone and alprazolam to C.F. The Government further alleged that no credible physical examination had been performed on C.F. and that the exam results, as well

[43] The Respondent's explanation of the Tennessee standards was admitted, not as expert testimony, as the Respondent had not been qualified as an expert to opine on the Tennessee standards, but as reflecting his understanding of the guidelines to explain why he took or declined to take certain action.

as medical history, did not justify the continued prescribing of controlled substances. The Government further alleged that no meaningful follow-up physical exam was repeated, that supported diagnostic studies were not ordered, and that the Respondent failed to determine a chronic pain etiology. The Government further alleged that the Respondent ignored suspicious drug screen results which indicated illegal drug use. The Government alleged that much of the medical record for C.F. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. Although the Respondent documented that the patient provided ''informed consent,'' no informed consent document could be located. Additionally, the Government alleged the Respondent failed to address substantial evidence that C.F. was engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. 63–6–214(b)(13).

The Respondent explained that Patient C.F. had a stab wound to the chest, requiring heart surgery, resulting in residual chronic pain. Tr. 601. The Respondent reported he took a medical history, performed a physical exam, an adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse. Tr. 601–02. The Respondent noted that he had the benefit of confirmatory records from Vanderbilt University Medical Center. Tr. 602.

Dr. Kennedy testified that the chart revealed C.F. was being treated for chronic pain due to trauma, and unspecified inflammatory polyarthropathy. Tr. 268; GX 12. Dr. Kennedy conceded C.F. had suffered stab wounds to the chest requiring open heart surgery, which can cause long-term neuropathic pain. Tr. 451–53. Although in his PHB, the Respondent characterizes Dr. Kennedy's criticism of the Respondent's subject treatment as failing to order tests, Dr. Kennedy had more extensive criticism than that. Dr. Kennedy opined that the history, physical exams, the pain and physical and psychological functioning, the potential for substance abuse, written treatment plan, and alternate treatment considerations were each inadequate, and did not justify the controlled substance prescriptions.[44] Tr. 269–70, 285, 455; GX 11 at 106; GX 12, at 7. Dr. Kennedy noted the Respondent did not discuss the risks and benefits of controlled substance medications. Tr. 285. The physical exam notes revealed essentially normal findings, however the electronic records for this visit failed to include these findings. Tr. 271; GX 11 at 69. Instead, under physical exam, the same language duplicated so often in the records, is included. Tr. 272. There were no credible follow up physical exams, supporting studies, and no reasonable pain etiology. Tr. 272; GX 12 at 5, 6. The ROS indications were identically repeated in other charts. Tr. 272–73. Dr. Kennedy noted that the language in the general exam, ''patient is alert and oriented'' is similarly repeated 102 times throughout the records. Dr. Kennedy reported inconsistent UDSs for C.F., collected on July 2, 2018, and thereafter. Tr. 273–80, 282; GX 11 at 9, 23, 24, 25, 28, 33, 44, 47, 54, 69, 78, 111, 117; GX 20. Even more concerning, C.F.'s UDS result was negative for all of the medications she was prescribed. Tr. 275–77. C.F. also tested positive for cocaine and marihuana. Tr. 277, 280. An inconsistent drug screen on July 26, 2017, is not mentioned in the medical records. Tr. 288–89. Although the records repeatedly noted that, ''patient counseled at length on unsatisfactory UDS,'' Dr. Kennedy credibly testified that this was insufficient under Tennessee standards to address C.F.'s drug abuse and diversion. Tr. 280, 284. I credit Dr. Kennedy's assessment regarding the Respondent's deficient handling of C.F.'s ongoing drug abuse and diversion.

On May 3, 2017, C.F. tested positive for buprenorphine, a medication typically used to treat opioid use disorder. Tr. 281–82. The Respondent had not prescribed it. Although the Respondent explained that the MED prescribed to C.F. was a relatively low dose, Tr. 603–05; in light of C.F.'s continued drug abuse and diversion, Dr. Kennedy opined that the Respondent continued to improperly prescribe controlled substances without making a bona fide effort to cure C.F.'s addiction. Tr. 284. I agree.

The Respondent prescribed alprazolam for anxiety and insomnia. Tr. 286; GX 11 at 39. However, the supporting indications are identical to the other patients who were diagnosed with anxiety and insomnia. Tr. 286–87. The Respondent did not maintain complete and accurate records for C.F. Tr. 286. Dr. Kennedy concluded that the controlled substance prescriptions issued to C.F. were outside the usual course of professional practice. Tr. 287. For the reasons detailed, I concur. I credit Dr. Kennedy's expert opinions and find that the Respondent's subject prescribing to C.F. was in violation of Tennessee regulations, and below the Tennessee standards.

[In accordance with Dr. Kennedy's credible and unrebutted expert testimony, and for the reasons above, I find that the sixteen identified prescriptions for alprazolam and oxycodone that Respondent issued to C.F. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of C.F.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for C.F.'s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for C.F. Finally, in accordance with Dr. Kennedy's testimony, I find that C.F. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent.]

Patient B.C.

The Government alleges that from August 2014 through August 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone, oxymorphone, alprazolam, and carisoprodol to B.C. The Government further alleged that no credible physical examination had been performed on B.C. and that the exam results, as well as medical history, did not justify the continued prescribing of controlled substances. The Government further alleged that no meaningful follow-up physical exam was repeated, that confirmatory diagnostic studies were not ordered, and that the Respondent failed to determine a chronic pain etiology. The Government further alleged that the Respondent ignored suspicious drug screen results which indicated illegal drug use. The Government alleged that much of the medical record for B.C. was fabricated and seemed to be copied from records of other patients whose records

[44] The Agency has previously found based on the expert testimony that where the respondent: (1) ''gave inadequate examinations or none at all;'' (2) ignored the results of tests; and (3) ''took no precautions against misuse and diversion'' of controlled substances, the evidence established that the respondent exceeded the bounds of professional practice. *Carlos Gonzalez, M.D.,* 76 FR 63,118, 63,141 (2011) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975)).

contained identically worded assessments. Although the Respondent documented that the patient provided ''informed consent,'' no informed consent document could be located.

Dr. Kennedy identified his summary chart for B.C. Tr. 289–90; GX 13; GX 14. B.C. was being treated for chronic pain syndrome. B.C. was referred from the Clark County Jail, on December 19, 2012,[45] a potentially challenging patient. Tr. 458–59. Although not revealed in the chart, Respondent testified that B.C. had previously been a patient of the Respondent. The Respondent maintained that he took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated his history and potential for substance abuse, and prepared a written treatment plan. Tr. 608.

Dr. Kennedy disagreed, claiming the Respondent did not take an adequate medical history. Tr. 304. Although a physical exam was evident, Dr. Kennedy testified that it was insufficient and non-supportive to justify prescribing the medications prescribed. Tr. 290–91, 304; GX 13 at 169; GX 14 at 7; GX 22. Dr. Kennedy asserted the Respondent did not make an adequate assessment of pain, and physical and psychological function, of history of substance abuse, coexisting diseases and conditions, written treatment plan or alternate treatments. Tr. 304–06. He did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 306. There were no radiologic studies ordered. Tr. 303. There were no prior medical records ordered or obtained, but the records did include hospital records. Tr. 303, 459–60. Although the Respondent described the extensive forms each patient is required to fill out at the initial visit, some of the described forms, which were referenced in B.C.'s chart, were missing from the Respondent's records. Tr. 628–29; GX 13 at 5. The Respondent explained that some records were lost in 2014.[46] Tr. 630. However, the missing records were not recreated despite B.C. being a long-term patient. Tr. 630.

The Respondent explained why he obtained and kept pharmacy printouts in his records. They are easier and quicker to obtain than medical records. Tr. 606. The pharmacy printout informs how long the patient has been prescribed medications, changes in dosage, and the prescriber. Tr. 607.

Dr. Kennedy noted indications from the ROS were duplicated throughout the records. Of 141 encounters, the ROS language was duplicated 140 times, while the physical exam language was duplicated 134 times. Tr. 291–92. B.C. had serious health issues, including Hodgkins lymphoma, a cancer of the lymphatic system. Tr. 293. Dr. Kennedy identified a document in the chart indicating B.C. had been dismissed from a prior physician, a clear red flag which was not resolved. Tr. 293–94; GX 13 at 188.

Dr. Kennedy noted the actual pain level was left blank at nine consecutive encounters, suggesting it is being added later, a further indication of fabricated records. Tr. 294–95; GX 13 at 159; GX 14 at 8. Dr. Kennedy opined the Respondent did not maintain accurate and complete records. Tr. 306. One entry reveals, ''patient lied about his prescriptions,'' an alarming red flag left unaddressed by the Respondent. Tr. 296; GX 13 at 169. Despite noting that the ''patient lied,'' the Respondent issued controlled medications and ''held'' up UDS for a month. Tr. 297. This is outside the usual course of professional practice. B.C. continued to have inconsistent UDS results, which were insufficiently addressed by the Respondent. Tr. 297–98; GX 13 at 33, 79, 150, 155, 156, 158, 164, 165. The Respondent countered that each of the Respondent's patient records contained the instruction, ''rule out doctor shopping'', which was a prompt to review the Tennessee PDMP to determine if the patient was obtaining controlled substances from multiple physicians. Tr. 608. Although ruling out doctor shopping is appropriate and necessary action, it does not excuse the failure to adequately address B.C.'s drug abuse and other red flags. I credit Dr. Kennedy's findings, and I find that the information contained in B.C.'s chart did not justify the controlled medications prescribed by the Respondent, nor support that they were issued in the usual course of professional practice. Tr. 307–08.

[In accordance with Dr. Kennedy's credible and unrebutted expert testimony, and for the reasons above, I find that the eighteen identified prescriptions for alprazolam, oxymorphone, carisoprodol, and oxycodone that Respondent issued to B.C. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of B.C.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for B.C.'s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for B.C. Finally, in accordance with Dr. Kennedy's testimony, I find that B.C.'s records included unresolved inconsistent drug screens, a red flag that was not adequately addressed by Respondent.]

Patient M.H.

The Government alleges that from August 2014 through February 2018, the Respondent regularly issued prescriptions for large quantities of alprazolam, carisoprodol, oxycodone, and oxymorphone to M.H. The Government further alleges the Respondent diagnosed M.H. with ''chronic pain syndrome'' even though the Respondent made no attempt to diagnose a specific pain etiology. The Government further alleged that that the Respondent failed to obtain diagnostic studies and current medical records from M.H.'s other medical providers and that the results of the physical examination and medical history did not justify the continued prescribing of controlled substances. The Government alleged the Respondent ignored a major surgical intervention that occurred in September 2016 as well as an abnormal drug screen. As such, the Government concluded that much of the medical record for M.H. was fabricated and seemed to be copied from records of other patients whose records contained identically-worded assessments. The Respondent also documented that the patient provided ''informed consent'' when no informed consent document could be located. The Government alleged that, in some cases, the Respondent failed to repeat certain physical exams after the initial encounter with M.H., despite the fact the Respondent provided him with prescriptions for controlled substances for more than three years.

The Respondent explained Patient M.H. presented with a post gunshot wound to the abdomen and chronic low

[45] The Respondent noted the pain management guidelines have changed since then. Tr. 605. [It appears that Tennessee has been regulating authority for physicians to prescribe for treatment of pain since 2014. As the changes seem to have taken place well before the prescribing of the controlled substances at issue in this case, this information is not material to my decision.]

[46] I ruled the evidence of lost files in 2014 inadmissible as unnoticed and not reasonably anticipated by the Government, representing surprise.

back pain secondary to degenerative disc disease. Tr. 608. According to Respondent, he had already been treated for pain management. He had a history of extensive spinal surgery at Vanderbilt University Medical Center, including a laminectomy. Tr. 609–11. The Respondent testified that he prescribed a lower MME than the surgeon prescribed post-operative at Vanderbilt. Tr. 611.

Dr. Kennedy identified his summary chart for Patient M.H. Tr. 309; GX 15; GX 16. The chart reveals M.H. was being treated for chronic pain syndrome. GX 15 at 62, 63. The physical exam indications are identical to those repeated throughout the medical records and, in Dr. Kennedy's opinion, do not support any chronic pain diagnosis. Tr. 311. The records reveal M.H. suffered a gunshot wound in 2008, and although serious, Dr. Kennedy opined that would not in itself justify pain medication eight years later. Tr. 323. Dr. Kennedy assessed the Respondent's treatment as outside the scope of acceptable medical practice because the Respondent did not make an adequate assessment of pain, and physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan or alternate treatments. Tr. 312, 326–28. The Respondent did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 328. M.H. had inconsistent UDSs. Tr. 314–20; GX 15 at 36, 39, 40, 47, 49, 53, 56, 63. Although several inconsistent UDS were noted in the chart, there were typically no notes of discussions. The Respondent failed to adequately address the UDS. Tr. 314–20.

During his treatment with the Respondent, M.H. underwent a serious and complex spinal surgery, a major surgery. Tr. 320–22, 462–63; GX 15 at 26; GX 16, at 9. M.H. was seen by the Respondent the day after his release from the hospital. GX 15 at 48. Despite his recent, major surgery, there is no mention of the surgery in the encounter notes. Tr. 322–23. The encounter notes are identical to all the other encounter notes for M.H. Tr. 323; GX 15 at 48. The Respondent conceded his medical findings as to Patient M.H. for the visit just prior to M.H.'s major back surgery are the same as the Respondent's findings for the visit the day after the surgery. Tr. 637–38; GX 15 at 48–50. The Respondent explained that the subject findings were based on ''history.'' Tr. 638. Put another way, Respondent carried forward the exam indications from the pre-surgery visit to the post-surgery visit.

There is no updated physical exam, as Dr. Kennedy opined would be required. Tr. 324. The PE and HPI notes are the same as those the four months prior to the spinal surgery, which is not credible. Tr. 324–25, 491–92; GX 15 at 49, 51. Dr. Kennedy opined that the Respondent did not maintain accurate and complete records as to M.H. Tr. 328. Dr. Kennedy reviewed the prescriptions issued. Tr. 325; GX 19 at 1–13. He opined that the chart, including the number of inconsistent UDS, reveals that M.H. was addicted to controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction. Tr. 325. The Respondent conceded the chart reports that M.H. has been ''compliant,'' however, on the next page of the chart, it reports M.H. had an inconsistent UDS. Tr. 638–40; GX 15 at 48–49. The Respondent explained that the inconsistent UDS related to the point of care test, not the confirmatory lab test, so the chart was accurate in that instance. Tr. 640. However, even if the inconsistent UDS result were at the point of care, as discussed *supra,* the record discloses there were eight of them, some of which went completely unaddressed within the records. I credit Dr. Kennedy's opinion that the Respondent's failure to resolve the red flag arising from inconsistent UDS rendered the subsequent prescribing outside the Tennessee standard of care.

Dr. Kennedy opined the subject prescriptions were issued outside the usual course of professional practice. Tr. 329–30, 493. I credit Dr. Kennedy's findings, and find that the Respondent's controlled substance prescribing were in violation of Tennessee regulations and the Tennessee standards.

[In accordance with Dr. Kennedy's credible and unrebutted expert testimony, and for the reasons above, I find that the approximately fifteen identified prescriptions for alprazolam, oxycodone, and oxymorphone that Respondent issued to M.H. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of M.H.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for M.H.'s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for M.H. Finally, in accordance with Dr. Kennedy's testimony, I find that M.H. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent.]

Patient M.P.

The Government alleges that from September 2016 through April 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone and oxymorphone to M.P. The Government alleges that the Respondent failed to request and obtain past medical records, the Respondent failed to order any radiographic studies, and that the physical examinations of M.P., including follow-up exams, were substandard and not credible. The Government alleged that the Respondent failed to document any evidence to support a pain etiology and that the Respondent failed to properly address M.P.'s substance abuse disorder despite the fact that she suffered a heroin overdose in the Respondent's waiting room. As a result, the Government alleged there were no objective findings to justify the continued prescribing of oxycodone and oxymorphone. The Government alleges that much of the medical record for M.P. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. The Respondent also documented that the patient provided ''informed consent'' when no informed consent document could be located in the medical record. Additionally, the Government alleged the Respondent failed to address substantial evidence that M.P. was engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN . § 63–6–214(b)(13).

The Respondent explained Patient M.P. was being managed for chronic pain. In her initial visit, she reported conflicting information regarding whether she had been in drug rehab treatment. Tr. 641–42; GX 7. The Respondent explained that he could only rely on the information provided by the patient. Tr. 642. The Respondent claimed that he took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse, and prepared a written treatment plan. Tr. 615–17.

Dr. Kennedy countered, noting he reviewed the prescriptions issued. Tr. 348–49; GX 21. He opined that the chart, including the number of

inconsistent UDS, reveals that M.P. was addicted to controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction, until after she overdosed on heroin. Tr. 348. The subject prescriptions, as well as those prescribed to the other charged patients, were dangerous and issued outside the usual course of professional practice. Tr. 352, 488–89.

Dr. Kennedy reported M.P. was being treated for low back, neck, hip and shoulder pain. Tr. 331; GX 8. She was later diagnosed with degenerative disc disease and right shoulder pain. Although a physical exam was performed, it was inadequate to substantiate the diagnoses. Tr. 331–34, 339–40, 343; GX 7 at 2. A mechanical shoulder exam and range of motion back and neck exam should have been performed. Dr. Kennedy opined that Respondent did not make an adequate assessment of pain, nor physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan nor alternate treatments. Tr. 349–51. He did not conduct any periodic reviews, nor discuss the risks and benefits of the use of controlled substances. Tr. 349–50. Dr. Kennedy stated that M.P.'s employment as a server, working 45–60 hours per week is inconsistent with her ''occupational disability'' score of 9 or 10, a significant conflict. Tr. 344–45; GX 7 at 3, 9, 10. Dr. Kennedy noted the hand-written exam notes did not appear in the electronic medical records. Tr. 325–36; GX 7 at 68. Instead the PE notes duplicated throughout the records appears. Tr. 336, 351. The pain level is reported as 9, which is inconsistent with the PE indications. Dr. Kennedy indicated notes generated at the initial visit appeared to be a reminder to obtain certain prior medical records from Dr. M. Tr. 337, 468; GX 7 at 1, 68. Those same notes appear in the record repeatedly thereafter. Tr. 337; GX 7 at 59. Other than the requested pharmacy report, the prior records were never obtained. Tr. 338–39. The Respondent explained that in September of 2016, the Respondent requested dismissal records, an X-ray, and an MRI from Dr. M. Tr. 642–44; GX 7 at 48. Yet, eighteen months later, the Respondent still had not received the requested records. Tr. 644; GX 7 at 59. There is no documentary proof records were ever requested.

Dr. Kennedy concluded the Respondent did not maintain accurate and complete records as to M.P. Tr. 350. At M.P.'s initial visit a UDS was performed revealing inconsistent results, which were never addressed in the records. Tr. 338; GX 7 at 19, 68. Notes reveal M.B. had been terminated from a prior physician, a red flag. Tr. 343. The records did reveal a monitoring of the Tennessee PDMP, and a successful pill count, both positive steps by the Respondent. Tr. 470. There were emergency room notes which revealed she was admitted on April 17, 2018 and released on April 18 for apparent heroin overdose, which occurred in the Respondent's waiting room. Tr. 340–41; GX 7 at 25.

The Respondent explained those events. He testified that M.P. came to the clinic overdosing on heroin. Tr. 342, 611–12. She had to be resuscitated until EMS was able to reverse the effects of heroin with Narcan. Tr. 612. In the post-overdose notes the Respondent took an extensive history again regarding her drug use. Following the heroin overdose, the determination was made that she needed treatment of Suboxone and no further opioid prescriptions. Tr. 616. He directed she cannot be on pain management but must be on opioid abuse treatment. So, the Respondent started her on Suboxone. Tr. 613. The Respondent explained his understanding of Suboxone induction. The first type of induction therapy is by observation. He stated that you give the patient Suboxone and observe them until they reach the point of withdrawal. The other form of induction is to give the patient Suboxone and send them home without observation by the physician. Tr. 612–14. According to Respondent, M.P. was initially receptive to drug treatment, but later changed clinics. Tr. 615.

Dr. Kennedy viewed Respondent's prescribing of Suboxone as dangerous and outside the standard of care. Tr. 342, 371–73, 465–66. As the patient was shown to be on heroin, a UDS would be necessary to determine if she had heroin in her system before prescribing buprenorphine (Suboxone), which in conjunction with heroin could result in permanent withdrawal. Tr. 343. The Respondent argues in his PHB that a successful UDS was conducted. However, I do not find a successful UDS in the record prior to the Respondent prescribing Suboxone. There were inconsistent UDS in the records for M.P. Tr. 346–; GX 7 at 48, 59. I credit Dr. Kennedy's findings. The Respondent's prescribing to M.B. was in violation of Tennessee regulations and Tennessee standards. The Suboxone prescription without determining her heroin level was dangerous and outside the course of professional practice. The Respondent's failure to timely address M.P.'s inconsistent UDS results was outside the Tennessee standards.

[In accordance with Dr. Kennedy's credible and unrebutted testimony, and for the reasons above, I find that the sixteen identified prescriptions for oxycodone and oxymorphone and the prescription for buprenorphine that Respondent issued to M.P. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of M.P.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for M.P.'s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for M.P. Finally, in accordance with Dr. Kennedy's testimony, I find that M.P. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent until after she overdosed in his office.]

Material Falsification

In its GSPHS, the Government alleged that, on November 6, 2019, the Respondent made a material misrepresentation in his renewal application for his Tennessee-based DEA COR, W18070589C. Specifically, in response to liability question three, the Respondent answered ''no,'' which he knew or should have known to be a false response. GX 26. Liability question three queries whether the applicant has ever surrendered for cause, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or have any such action pending. An affirmative answer to question 3 would trigger an investigation by a diversion investigator whether to issue the registration or to deny it. The Respondent answered ''No'' to question 3.

In support, the Government cites to the State of Tennessee Department of Health, Notice of Charges and Memorandum for Assessment of Civil Penalties, dated May 2018. GX 29. [In this document, the state requested that ''Respondent's certificate to operate a Pain Management Clinic . . . be suspended, revoked, or otherwise disciplined.'' GX 29, at 25.] A year later

in May 2019, the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part 3, issued an order Reversing Denial of Stay, but Accompanying Stay with Conditions. GX 27. The stay was conditioned upon the Respondent ''not writing any prescriptions during the pendency of the stay; . . . and/or not providing direct patient care including but not limited to diagnosing, treating, operating on or prescribing for any person.'' GX 27, at 2. Therefore, as of May 2019, the Conditions preclude the Respondent from writing prescriptions or providing direct patient care during the pendency of the stay and were reportable restrictions. When asked on his November 6, 2019 application whether Respondent had ever had a state professional license or controlled substance registration revoked, suspended, or restricted or had any such action pending, he was required to, but did not, disclose these events.*X [47] Therefore, I find clear, unequivocal, and convincing evidence that Respondent submitted a registration application containing a false answer to the third Liability question.

[My finding about Respondent's submission of a false answer involves restrictions on Respondent's state license to dispense controlled substances. *Id.* In setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Accordingly, it is clear that having authorization to dispense controlled substances is a prerequisite to my ability to grant an applicant's application. Respondent's false response to the third Liability question directly implicated my statutorily-mandated analysis and my decision by depriving me of legally relevant facts when I evaluated Respondent's registration renewal application. *See Frank Joseph Stirlacci, M.D.,* 85 FR 45,229, 45,235 (2020). Accordingly, I find, based on the CSA and the analysis underlying multiple Supreme Court decisions explaining ''materiality,'' that the falsity Respondent submitted was material. *Frank Joseph Stirlacci, M.D.,* 85 FR at 45,235.] *Y *Z

Government's Burden of Proof and Establishment of a Prima Facie Case

Based upon my review of each of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f). At the outset, I find that the Government has demonstrated and met its burden of proof in support of its allegations relating to the prescribing of controlled substances to patients UC, M.P., M.W., C.F., B.C., and M.H. The Government has also sustained their burden as to the material misrepresentation allegation.

Public Interest Determination: The Standard

[Under Section 304 of the CSA, ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4).] [48] Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with the ''the public interest:''

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). ''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see also Morall* v. *DEA* at 173–74; *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422, 16424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d at 482; *see also Morall,* 412 F.3d at 173. [Omitted for brevity.] The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Krishna-Iyer, M.D.,* 74 FR at 462.

The Government's case invoking the public interest factors of 21 U.S.C. 823(f) seeks the revocation of the Respondent's COR based primarily on conduct most aptly considered under Public Interest Factor's [Two and] Four.[49]

[Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances] *AA

According to the Controlled Substances Act's (hereinafter, CSA) implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription,

*X Omitted text. The Government also alleged that Respondent's surrender of his pain clinic's license also warranted an affirmative response to question 3 on Respondent's personal application. I find that I do not need to reach a decision on this evidence as the Government has already presented ample evidence that Respondent materially falsified his application when he failed to report that his authority to dispense controlled substances was restricted.

[47] [Omitted the original text containing this footnote.]

*Y This language replaces the ALJ's original analysis for clarity.

*Z Omitted ALJ's discussion of the pain clinic's license. *See supra* n. *X. I have also consolidated the ALJ's original section entitled ''Conditions of Stay'' with the preceding paragraph for brevity.

[48] [This text replaces the ALJ's original text and omits his original footnote for clarity.]

[49] [Where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011) (''The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.''). Here, to the extent that Tennessee's decision not to revoke or suspend Respondent's individual authority to handle controlled substances could weigh in his favor, I find that any such weight would be significantly reduced by the circumstances of the loss of his practice's license, and the pending nature of the state action on his individual license.] Likewise, the record contains no evidence that the Respondent has been convicted of a crime related to controlled substances (Factor Three).

*AA The ALJ only evaluated the evidence under Factor 4. However, Respondent's dispensing experience is clearly relevant to my determination as to whether or not Respondent's continued registration is consistent with the public interest, and I have made changes throughout this section accordingly.

that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

I found above that the Government's expert credibly testified as supported by Tennessee law, that the standard of care requires a practitioner, before prescribing controlled substances, to take an adequate medical history including an assessment of the patient's pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for the patient's individual needs and to discuss the risks and benefits of the use of controlled substances with the patient. Additionally, I found that practitioners are required to maintain complete and accurate records for their patients. I also found above that Respondent issued approximately ninety-five controlled substance prescriptions outside the usual course of professional practice and beneath the standard of care. This is because for each of the relevant prescriptions, I found that the Respondent failed to take an adequate medical history including an assessment of each patient's pain history and potential for substance abuse; perform and document an adequate physical examination; and/or create a legitimate written treatment plan for each patient's individual needs and/or discuss the risks and benefits of using controlled substances with the patient. I also found that each of the relevant prescriptions were issued outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records.

Respondent repeatedly issued prescriptions without complying with the applicable standard of care and state law thus demonstrating that his conduct was not an isolated occurrence, but occurred with multiple patients. *See Kaniz Khan Jaffery,* 85 FR 45,667, 45,685 (2020). For example, Respondent's medical records for each of the individuals at issue had verbatim language repeated throughout the relevant time frame stating, ''Patient has a long standing h/o insomnia and anxiety for several years. Anxiety symptoms include sob, palpitations, sweating, dizziness, shaking, insomnia, irritability, pacing, moodiness and feeling faint. Right now no headache, no dizziness, no nausea, no vomiting, no abdominal pain, no diarrhoea [sic.], no constipation, no sob, no chest pain, no palpitations.'' GX 9, at 85; GX 11, at 39; Tr. 286–87. This verbatim language was included in each patient's record and in UC's records to which UC testified credibly that he did not report having any of the anxiety symptoms identified in the chart.

Agency decisions highlight the Agency's interpretation that ''[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.' '' *Cynthia M. Cadet, M.D.,* 76 FR 19,450, 19,464 (2011). DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that he prescribed a controlled substance—adequate documentation is critical to that assessment. *See Kaniz-Khan Jaffery,* 85 FR at 45,686. Further, as Dr. Kennedy testified, ''maintaining a patient on scheduled medications . . . sometimes at high dosages, without having honest, accurate, complete medical records is dangerous.'' Tr. 352–53. This is because, according to Dr. Kennedy, ''those medical records will instruct other people who look at them as to what the motivation was for the treatment . . . [a]nd if what is documented in the medical record simply doesn't made sense or is something that is in conflict . . . [t]hat can . . . present a dangerous situation.'' Tr. 353. Therefore, recordkeeping is not only important for compliance, but also for the safety of the patients.

DEA decisions have found that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28,643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998). ''Diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .' '' *Id.* (citing *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014)). In this case, I have found that Respondent issued controlled substance prescriptions without complying with his obligations under the CSA and Tennessee law. *See George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010)).

With regard to Tennessee law, I find that in issuing controlled substances prescriptions that were outside the usual course of professional practice and beneath the standard of care, Respondent issued prescriptions that were ''not in the course of professional practice'' in violation of TENN. CODE ANN. § 63–6–2l4(b)(12). The Tennessee guidelines require that a physician: (1) Take a documented medical history; (2) conduct a physical examination; and (3) perform an adequate ''assessment and consideration of the [patient's] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.'' TENN. COMP. R. & REGS. 0880–02–.14(6)(e)(3)(i). I found above that respondent failed to conduct an adequate assessment and consideration of the pain and potential for substance abuse and failed to conduct a physical examination for each of the individuals at issue including UC. Additionally, Rule 0880–02–.14 (6)(e) requires physicians to create a ''written treatment plan tailored for the individual needs of the patient'' that considers the patient's ''pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.'' I found above that respondent failed to prepare a tailored written treatment plan for each of the individuals at issue including UC. Tennessee guidelines also requires the physician to ''discuss the risks and benefits of the use of controlled substances,'' which I found above that Respondent failed to do for UC, C.F., B.C., M.H., and M.P., and ''keep [c]omplete and accurate records of the care,'' which Respondent failed to do for each of the individuals at issue including UC. *Id.* at 0880–02-.14(6)(e)(3)(ii)–(v).

Additionally, TENN. CODE ANN. § 63–6–214(b)(13) prohibits a physician from prescribing controlled substances to a person ''addicted to the habit of using controlled substances'' without ''making a bona fide effort to cure the [patient's] habit.'' Crediting Dr. Kennedy's testimony, I found above that Respondent acted outside the bounds of this law with regard to patients M.W., C.F., M.H., and M.P.]

The evidence is clear the Respondent violated the Tennessee regulations alleged, and the Tennessee professional standards. The Tennessee regulations are related to controlled substances. [Overall, I find that in issuing ninety-five prescriptions beneath the

applicable standard of care and outside the usual course of professional practice in Tennessee, Respondent violated 21 CFR 1306.04(a) in addition to Tennessee law, and these violations of law weigh against Respondent's continued registration under Public Interest Factors 2 and 4.] [50]

Sanctions *[BB]

[Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest, the burden shifts to the Respondent to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Respondent has made minimal effort to establish that he can be entrusted with a registration.

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 259 (2006). A clear purpose of this authority is to ''bar[ ] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.'' *Id.* at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not he has presented ''sufficient mitigating evidence to assure the Administrator that he can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23,853; *John H. Kennedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).]

While the Respondent has conceded that his medical charts contained several errors he never accepted responsibility for [the violations I have found]. His testimony defending the identical indications among his patients in support of his anxiety and insomnia diagnoses was not at all credible. The lack of a credible explanation for the inclusion of results in UC's chart of tests and examinations which did not take place weighs heavily against a finding of acceptance of responsibility. Furthermore, although he testified, he did not address the material falsification allegation. I therefore find that any acceptance of responsibility has neither been unequivocal nor complete.

[In all, Respondent failed to explain why, in spite of his misconduct, he can be entrusted with a registration. ''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering ''magic words'' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 49,973 (2019). Here, having considered Respondent's case and statements, I am left with no confidence in Respondent's future compliance with the CSA.]

Egregiousness and Deterrence

[The Agency also looks to the egregiousness and extent of the misconduct which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases).] I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation. [Respondent issued approximately 95 prescriptions for controlled substances outside the usual course of professional practice and beneath the standard of care.] The proven misconduct involved fabricated medical charts, failure to meaningfully address serious and ongoing indications of drug abuse and diversion by several of his patients, as well as other red flags. The proven misconduct also involved the material falsification of his application for his CSA registration renewal in Tennessee.*[CC]

[In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case.] Allowing the Respondent to retain his COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite ignoring obvious signs of abuse, diversion and other serious red flags, the wholesale failure to maintain adequate, complete and accurate medical charts, and after making a material falsification on a renewal application. Revoking the Respondent's COR communicates to registrants that the DEA takes all of these failings under the CSA seriously and that severe violations will result in severe sanctions.

[Omitted.] *[DD]

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR at 387. The Respondent's material misrepresentation compounds the Respondent's instant burden. Although the Respondent offered some evidence of mitigation, even if considered, it has not overcome the loss of trust resulting from the allegations found herein.

[50] An expert's opinion that a doctor's treatment of patients fell below the standard of care is probative of whether the doctor violated 21 CFR 1306.04(a). *Bienvenido Tan, M.D.,* 76 FR 17,673, 17,681 (2011).

*[BB] I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

*[CC] Remaining analysis of egregiousness omitted for relevance.

*[DD] I agree with the ALJ that Respondent's testimony lacked credibility and I have given it little-to-no weight in reaching my decision. However, in light of Respondent's failure to unequivocally accept responsibility, it is not necessary for me to assess whether Respondent's testimony also lacked candor and I have therefore omitted the ALJ's discussion of this topic.

[There is simply no evidence that Respondent's behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.]

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. In evaluating Factors [Two and] Four of 21 U.S.C. 823(f), I find that the Respondent's COR is inconsistent with the public interest. Furthermore, I find that the Respondent has failed to overcome the Government's *prima facie* case by unequivocally accepting responsibility and establishing that he can be trusted with a registration.

Therefore, I recommend that the Respondent's DEA COR Control No. BO4959889 should be *revoked*, and that any pending applications for modification or renewal of the existing registration, including the pending application for a new DEA COR Control No. W18070589C, and any applications for additional registrations, be *denied*.

Mark M. Dowd,
U.S. Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. BO4959889 issued to Samson K. Orusa, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any other pending applications for renewal or modification of this registration, the pending application for new DEA COR Control No. W18070589C, as well as any other pending application of Samson K. Orusa, M.D., for registration in Tennessee. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–00952 Filed 1–18–22; 8:45 am]

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